Pennsylvania
Department of Health

Orally Dissolving Formulations Guidance

The Department of Health (Department), Bureau of Medical Marijuana (Bureau) is providing this guidance to all Medical Marijuana Organizations (MMOs) on orally dissolving formulations (ODFs) in the Pennsylvania Medical Marijuana Program.

The Bureau uses the term orally dissolving formulations (ODFs) to mean a hard or soft lozenge, troche or other route of administration (ROA) that is intended to be dissolved in the mouth and absorbed buccally or sublingually via the oral mucosal membrane (transmucosal). This is the only route of administration for ODFs that is consistent with the Medical Marijuana Act's prohibition at 35 P.S. § 10231.304(b)(2) against MMOs incorporating medical marijuana into edibles. ODFs approved by the Bureau fall under the topical/pill forms. 35 P.S. § 10231.303(b)(2)(i), (iii). Therefore, MMOs should refer to the product as ODFs, such as *troches, lozenges, orally disintegrating tablets (ODTs),* in all packaging and marketing, and contain text that clearly identifies the route(s) of administration (buccal, sublingual, transmucosal, or dissolve in the mouth). MMOs should not refer to the product as *edibles*.

ODFs cannot be designed for chewing as that would constitute incorporating medical marijuana into edible form, which is not permitted to be dispensed under law. See 35 P.S. § 10231.304. ODFs are intended for oral administration and only to dissolve in the mouth, but not to be chewed. Because ODFs are intended to be put in the mouth, ODFs therefore have the potential to be misused by patients, either intentionally or unintentionally, and present a heightened misuse risk by minors and/or non-patients. Given the above concerns, this guidance addresses:

1. Guidance on Strength Limits
2. Guidance on Additional Ingredients and Substances
3. Guidance on Flavors and Naming Conventions
4. Guidance on Appearance
5. Guidance on Packaging, Labeling, Advertising and Marketing

Pursuant to 28 Pa. Code § 1151a.28, a Grower/Processor is required to obtain Bureau pre-approval of every medical marijuana product.

Pursuant to 28 Pa. Code § 1151.27(f), a Grower/Processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect, or weight of the medical marijuana unless the grower/processor has first obtained prior written approval.

1. **Guidance on Strength Limits:**

   Consistent with balancing patients' need for ODFs with the specific safety concerns presented by ODFs as a form of medication, the Bureau considers the strength of proposed ODF in the pre-approval process. The Bureau has not identified a medical need for individual ODFs or for scored or segmented ODF bars containing greater than 100mg of medical marijuana derived THC. These strength limits per ODF and scored or segmented ODF bar are based on the misuse concerns outlined above, including if a patient were to disregard the route of administration, misunderstand the dose per serving, and/or overconsume before the onset of effects, or where a non-patient child might access medication.

a. **Recommended Delta-9-tetrahydrocannabinol (Delta-9 THC) strength limits – per single dose of one ODF:**

   i. **THC** is limited to 100mg total of PA medical marijuana derived Delta-9 THC per individual dose, per (one single) ODF, or per one scored/segmented ODF bar in total.
   ii. Any ODF product that contains **minor cannabinoids** (including, but not limited to, CBD, CBG, CBN, CBC, THC-V) will be evaluated within the context of each product submission, on factors such as the supporting evidence for said minor cannabinoid and the strength of the cannabinoid.

b. **Recommended Delta-9-tetrahydrocannabinol (Delta-9 THC) strength limits – per unit or package of ODFs.** THC is limited to 1500mg total of Pennsylvania medical marijuana derived Delta-9 THC per unit or per package of ODFs. Any ODF product that contains **minor cannabinoids** (including, but not limited to, CBD, CBG, CBN, CBC, THC-V) will be evaluated within the context of each product approval request, on factors such as the supporting evidence for the minor cannabinoid and the strength of the cannabinoid.

c. **Required specific and consistent concentrations for each ODF.** Medical marijuana products are required to have a specific concentration of THC and total CBD as well as a consistent cannabinoid profile. 28 Pa. Code § 1151a.29(a). For ODFs, it is necessary for patients to know the proper dosage to be able to avoid potential overconsumption. As such:

   i. For each individual ODF to meet the required consistency in size, shape, and dosage, ODFs should be created via a mold process (e.g. pour and scrape, piping, or automatic depositor). Creation of individual ODFs by hand (e.g. rolling, manipulating, stretching/pulling, or manual cutting of bulk product) is not recommended because it increases the likelihood of inconsistent doses and potential overconsumption.
   ii. Segmented or scored ODFs should contain the same dosage for each section. A scored or segmented ODF bar should not exceed 100mg THC in total. For example, a scored ODF bar with 100mg THC in total may contain 5 equal pieces of 20mg THC per piece. Score marks on an ODF bar are recommended so that patients can snap, break or cut with precision.

2. **<u>Guidance on Added Ingredients and Substances:</u>**

a. All proposed ingredients and sub-ingredients that are part of ODF manufacture must be detailed as instructed in the *Request for Approval: Medical Marijuana Product, Instrument or Device* form. This includes but is not limited to mold-release sprays, final coatings, and any added substances such as flavorings and colorants.

b. Any final outer ODF coating, including any non-stick ingredients, should not contain sugar, reverse-sugar, sour sanding or any sweeteners, souring-agents, or any other flavoring agents. Acceptable coatings include those coatings solely meant for non-stick purposes.

c. Active ingredients that furnish a pharmacological activity or direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease may not be added to the medical marijuana products, consistent with 35 P.S. § 10231.301(a)(14); 28 Pa Code § 1151a.27(f).

3. **Guidance on Flavors and Naming Conventions:**

   a. **Flavors.** ODF flavors should be traditional pharmaceutical preparations, real fruit, or plant cultivar(s). The Bureau evaluates flavors that appear on packaging and labeling for intentional or unintentional attractiveness to children, such as candy or dessert flavors, inappropriateness for a medical program, resemblance to a commercially available food or beverage product, or containing a design that would lead an individual to believe that the product is something other than medical marijuana, such as food or candy. 28 Pa. Code § 1151a.34(e)(1), (2), (4).

   b. **Naming Conventions**. When requesting a name that will appear on the packaging, dispensary menu systems and within marketing requests, MMOs should not use fictional or indeterminate flavor names, commercially available food or beverage names, candy/confectionary names, and/or names clearly attractive to children. 28 Pa. Code § 1151a.34(e)(1)(4).

   c. **Flavor Name Descriptors:**

      i. MMOs seeking to use brand names that are descriptors should understand that unsubstantiated medical claims, medical claims in relation to medical conditions other than the approved serious medical conditions, or descriptive text that is potentially attractive to children, are not consistent with the federal regulations governing prescription drug advertising. 28 Pa. Code § 1141a.50.

      ii. MMOs should be aware that marketing approved flavoring agents or colorants for potential or unsubstantiated health benefits on packaging/labeling, or on marketing or advertising is misleading. Flavors and colorants should be solely listed as such and packaging and labeling should not contain any text or image that implies a flavoring agent, or colorant imparts a health benefit or additional effect of any sort, consistent with 35 P.S. § 10231.301(a)(14); 28 Pa Code § 1151a.27(f).

4. **Guidance on Appearance:**

   a. Final form appearance of each ODF should be a basic geometric shape that can be consistently and effectively orally dissolved, such as, but not limited to: square, circle, triangle, semi-circle, oval, rectangle. ODFs should not resemble known candy or gummies or any similar candy, confectionary or edible item intended to be chewed.

   b. The Bureau strongly recommends a simple easy-to-distinguish THC warning symbol on ODFs (for example: THC! or THC outlined with another geometric shape) as this clearly identifies the product as containing medical marijuana, prevents misidentification as non-medical marijuana products, and decreases the potential for accidental ingestion.

   c. Score marks on an ODF bar or segmented ODF are permitted consistent as indicated above in Guidance on Strength Limits.

d. ODFs are not permitted to be produced in multi-color or multiple colors on one individual ODF, nor in excessively bright or neon colors. Each individual ODF **and** entire package or unit of ODFs should be only one, solid color.

5. **Guidance on Packaging, Labeling, Advertising and Marketing:**

a. Packaging and labeling requests for ODFs are reviewed for regulatory compliance in their totality, which includes review of the form and ROA for the product contained within the package, the relative potential for patient misuse and accidental consumption by minors and the public. More specifically:

i. Packaging, labeling, marketing, or advertising requests for ODFs should not contain the terms *ingestible, chewable, edible, gummy* or any similar term that suggests that this item is an edible.

ii. ODF packaging and labeling and any marketing or advertising should be evaluated for whether it could reasonably lead an individual to believe that the package contains anything other than medical marijuana, including recreational forms of marijuana, which are not appropriate for an exclusively medical program, or edible forms statutorily prohibited for dispensing. 28 Pa. Code § 1151a.34(e)(2).

iii. Packaging and labeling, as well as any advertising and/or marketing, for ODFs should not be attractive to children as outlined in 28 Pa. Code §§ 1151a.34(e)(4); 1161a.28(d)(4); 28 Pa. Code § 1141a.50.

iv. ODF packaging and labeling should clearly state that the ODF(s) contained in the package are medical marijuana products. 28 Pa. Code § 1151a.34(b)(5).

v. ODF packaging and labeling should conspicuously state the specific source of medical marijuana used in the manufacture of the ODF, (Examples: Distillate, Live Resin, RSO, Rosin, THC Diamonds) on the ODF packaging and labeling.

vi. The Bureau strongly recommends a simple, easy-to-distinguish THC warning symbol on packaging (for example: THC! or THC outlined with another geometric shape) because this clearly identifies the product as containing medical marijuana, prevents misidentification as non-medical marijuana products, and decreases the potential for accidental ingestion.

b. **Route of Administration (ROA):**

i. In order to ensure clarity and readability for patients in any packaging or marketing language, and consistency with the federal regulations governing prescription drug advertising, the Bureau will consider the following for ODF information referencing ROA:

1. Any packaging or labeling, advertising, or marketing, materials referencing, ROA of ODFs should always be referred to as either buccal, sublingual, and/or dissolve in the mouth.
2. All ODF product information including ROA, should be of a font type and size that is large enough to be legible for patients.
3. Crucial ODF information regarding the ROA should not be placed in "fine print" that is an overly small font size or designed in a way that may be overlooked or ignored.
4. ODF information regarding the ROA on any marketing should be immediately visible and not hidden within dense text or graphics. ODF information regarding the ROA should contrast clearly with the background color and/or graphics of all proposed ODF packaging and marketing materials.

c. **Dispensary Menus and Websites:**

i. On dispensary menus and/or websites both listing and displaying images of ODFs, product listings should be the actual images of Bureau-approved ODF products, approved ODF shapes and colors and Bureau-approved ODF packaging. Menu systems using imagery of ODF products and packaging that does not reflect the product and packaging as approved by the Bureau would not be consistent with Pennsylvania's laws.

ii. If an MMO is using a single third-party (or privately owned) menu system operator in multiple states and across medical and recreational markets, the MMO is responsible for ensuring all information on the menu system for this market are consistent with Pennsylvania's laws and the Federal regulations governing prescription drug advertising and marketing.

iii. A menu system that displays images of products not approved for use in Pennsylvania is not consistent with Pennsylvania's laws and is prohibited. The public dispensary menu systems displayed for Pennsylvania patients, including written ODF descriptions on those menus, should not include any terms restricted in Pennsylvania. Furthermore, within the Seed-to-Sale system and in the product database, categorizations and terms should adhere to these guidelines. For example, but not all inclusive, the terms *orally dissolving formulations, ingestibles,* or *troches* may be used; *edibles* may not. Edibles are not a permitted form of medical marijuana that can be sold by MMOs. 35 P.S. § 10231.302(b)(2); 28 Pa. Code § 1151a.28. Therefore, menu systems that categorize and describe any products as *edibles* are not consistent with Pennsylvania's laws.