NEW RULE I PACKAGING AND LABELING APPLICATION AND APPROVAL PROCESS; INITIAL REQUIREMENTS APPLICABLE TO ALL LICENSEES (1) For purposes of this rule, "marijuana product categories" mean any of the marijuana and marijuana products described in ARM 42.39.315 through 42.39.318 that are subject to the packaging and labeling requirements of 16-12-208, MCA.

(2) For purposes of this rule, a "unique marijuana product package" means:

(a) a prototype package for each of the marijuana product categories in (1); and

(b) within each of the marijuana product categories, a package that contains variations in graphic or design elements.

(3) A unique marijuana product package does not mean a package that depicts flavor variation without an accompanying change in graphic or design, or a different package size, or package color.

(4) All applicants, whether as an initial license applicant or existing licensee, must submit an application to the department, on a form provided by the department, for approval of the labeling of each marijuana product category intended for sale to customers.

(a) an applicant must submit a separate application for each label.

(b) an applicant must submit only one template label for each marijuana product type. Except as provided in (d), a new label application is not required when the marijuana facts panel information changes for disclosures such as levels of THC, THCa, CBD, or CBDa, date of harvest, strain name, or ingredients.

(c) An applicant that sells marijuana products to registered cardholders with THC potency levels in excess of the limits set in 16-12-224, MCA, must submit a separate application and label template for those products.

(5) An applicant must apply to the department, on a form provided by the department, for approval for the packaging of each unique marijuana product package.

(a) an applicant must submit a separate application for each unique marijuana product package.

(b) an applicant must provide a picture or accurate, detailed rendering and a description of the product to be placed in each unique marijuana product package.

(6) An applicant must submit a separate application for each exit package type it will use. If the applicant intends to use the same exit package type in multiple sizes, it may submit each size under the same application. Exit packaging must comply with ARM 42.39.319(2).

(7) All applications and required attachments, such as photographs product descriptions, renderings of proposed labels, and proposed packaging shall be submitted electronically to the department via its online portal.

(8) An applicant must submit the following fees to the department:

(a) $25 per label application.

(b) $10 per package application.

(9) The department shall review each application and shall notify an applicant, in writing, whether the label or package has been approved or rejected.

(10) Whenever the department returns an application for correction to the label or package, it shall notify an applicant, in writing, of the deficiencies or issues with the application or submitted label or package.

(11) An applicant may resubmit a label or package once under the original application within ten days after the date of the department's first return for correction without paying another application fee. If the applicant fails to respond within ten days, the application shall be denied.

(12) If the department returns a label or package application a second time, it shall notify an applicant, in writing, of the deficiencies or issues with the proposed package or label and that the application shall be denied.

(13) An applicant whose application is denied under (11) or (12) must reapply and pay a new application fee.

(14) In order to fully implement the packaging and labeling requirements of the Act, all licensees must submit their packaging and label applications to the department by July 1, 2022. Licensees may continue to use packaging and labeling that is compliant with the former Montana Medical Marijuana Act (Title 50, Chapter 46, MCA) during the pendency of the department's approval(s), provided the licensee's applications were submitted by July 1, 2022.

(15) A licensee that fails to submit applications for approval of packaging and labeling by July 1, 2022 shall be subject to disciplinary proceedings.

(16) All marijuana and marijuana products must be in approved packaging and affixed with approved labeling no later than January 1, 2023. Licensees shall repackage and/or relabel all marijuana and marijuana products on or before January 1, 2023, as necessary, to comply with this provision.

(17) A licensee must maintain approval letters for all product labels and packages at the licensed premises and shall make those letters available to department inspectors upon request.

AUTH: 16-12-112, MCA
IMP: 16-12-112, 16-12-208, 16-12-215, 16-12-224, MCA

REASONABLE NECESSITY: The department proposes to adopt New Rule I which is necessary for the department to implement the provisions of 16-12-208(8), MCA, by providing an application and approval process for the packaging and labeling of the marijuana or marijuana products described in ARM 42.39.314 through 42.39.319.

Section 16-12-208(8), MCA, requires a licensee or license applicant to submit both a package and a label application, using forms prescribed by the department, for department review and approval. New Rule I implements this directive and outlines the process for the submission of package and label approvals.

The inclusion of (1) is necessary - for the limited purpose of this rule - to cross-reference the marijuana product categories in ARM 42.39.315 through 42.39.318 that require a separate label application and lessen potential confusion from the marijuana product categories (and subcategories) defined in statute and ARM 42.39.102.

Sections (2) and (3) define what is, and what is not, a "unique marijuana product package" as guidance for when a product package requires an application and department approval.

Section (4) provides application requirements for a licensee or license

applicant for the approval of a label. Section (4) also clarifies that only one template label is required for each of the marijuana product categories in (1) unless the label will be used for a marijuana or a marijuana product that exceeds the THC potency levels in 16-12-224, MCA. Because there are additional label requirements for medical marijuana products (see ARM 42.39.315(8)), applicants must also submit a separate label template for the medical marijuana products so that the department can ensure the label satisfies all of the marijuana laws.

Section (5) sets forth what is required of a licensee an applicant or license applicant when it submits an application for the approval of a unique marijuana product package as defined in (2) and (3).

Section (6) provides the process for the approval of exit packaging. Each exit packaging configuration requires a separate application, unless an applicant intends to use the same exit package configuration in multiple sizes, in which case it can submit the differing sizes under one package approval application.

Section (7) sets forth how applicants may submit their applications. Pursuant to the authority in 16-12-208(8)(b), MCA, the department will require electronic applications and will only request a physical prototype, when necessary, to ensure that the label or package satisfies the marijuana laws.

Section (8) is proposed to establish application fee requirements. The department is required by 16-12-208(8)(d)(i), MCA, to establish these fees, and guided by 16-12-112(1)(q), MCA, in establishing the amount. The department contends the fees are reasonable given the amount of review and processing of label and packaging applications and the related submissions.

Sections (9) through (13) further explain the application submission process and also provides that an applicant may proceed under the initial application returned for correction and the conditions which require resubmittal of an application and payment of additional fees.

Section (14) provides a deadline by which all package and label applications must be submitted by for existing or known products. As new products are developed and new packaging is employed, applicants may submit approval for those products after this date.

Section (15) makes clear that licensees that fail to submit the mandatory package and label applications risk disciplinary proceedings.

Section (16) proposes to require a deadline for all licensees to submit their packaging and labeling applications for approval for all existing products in order to implement 16-12-208, MCA. The department is mindful of the challenges of converting labels and products for compliance under the marijuana laws. However, the Marijuana Regulation and Taxation Act became law in May 2021, and the department initiated its packaging and labeling rules (ARM 42.39.315 through 42.39.318) on October 22, 2021. The rules have been in effect since January 1, 2022 and licensees have been aware of program requirements.

Section (17) requires licensees to maintain approval letters on site at their licensed premises to show to inspectors, if requested. This will assist inspectors in determining whether packaging and labeling is complaint and will help shorten the length of time needed for an inspection by not requiring this determination be made on site.