Labeling and Packaging Guide:

The Cannabis Control Division (CCD) at the Montana Department of Revenue is providing this guide to explain the labeling, packaging, and exit packaging rules for marijuana and marijuana products. However, this guide should not be construed as a replacement for a thorough reading of the rules. The rules can be found here. (ARM 42.39.314 through ARM 42.39.319)

Licensees are required to follow the labeling and packaging rules, and it is their responsibility to know, understand, and operate within the rules.

The labeling and packaging rules apply to marijuana and marijuana products that are for ultimate sale to a consumer, registered cardholder, or their designated purchaser(s).

These rules do not apply to items that are undergoing lab sampling or testing, or bulk transfers of marijuana and marijuana products from one licensee to another.

There are general labeling requirements for all marijuana and marijuana products (adult-use and medical) under ARM 42.39.314.

In addition to general labeling requirements for all marijuana and marijuana products, there are additional labeling requirements for:

- marijuana flower ARM 42.39.315
- ingestible marijuana-infused products ARM 42.39.316
- non-ingestible marijuana-infused products ARM 42.39.317
- marijuana concentrates and extracts ARM 42.39.318

The packaging requirements for marijuana and marijuana products under ARM 42.39.319.

ARM 42.39.319 (2)(a)(b)(c) & (4) covers exit package requirements.
Who is required to get pre-approval for labeling and packaging?

Prior to selling, offering for sale, or transferring marijuana or marijuana product that is for ultimate sale to a consumer, registered cardholder, or the cardholder’s designated purchaser(s): all licensee or licensee applicants must submit and receive approval for labeling, packaging, and exit package applications.

Applications must be submitted using the form prescribed by the department. The department will review applications for compliance before approval.

The initial submission must be made electronically, as required by the department. The licensee or licensee applicant shall submit a physical prototype, if required, upon request.

What is the difference between labels, packages, and exit packages?

- The **label** is the **text, graphics, pictures, and logos** printed on or affixed to the product package. (If the package contains more than one label panel than all the panels are considered as being a part of one label).

- The **package or packaging** is the **physical structure** that holds and protects the product.

- The **exit package** is the child-resistant exit sealed container or package, for sold marijuana and marijuana products, that complies with federal child resistance standards. It is designed to be significantly difficult for children under 5 years of age to open but not difficult for adults to use properly.

As part of the application, the licensee/licensee applicant is required to submit documentation demonstrating that all exit packaging has been certified as child-resistant by a federally qualified third-party child-resistant package testing firm.
Example of label vs. package:

The label would be placed on this package (bottle) of cologne.

The **label** is the text, graphics, pictures, and logos printed on or affixed to the package.

This bottle is the package for the cologne.

The **package** is the physical structure that holds & protects the product.

The **label**:
1. identifies the product
2. provides information about the product and its use

The **package**:
1. encloses the product
2. protects the product from contamination & exposure to harmful substances

**When may applications be submitted to CCD? When are applications due?**
Beginning June 11, 2022, licensees may submit their label, package, and exit package applications to CCD for review. Applications and required attachments (such as photographs or accurate renderings of proposed labels, packages, and exit packages) shall be submitted electronically to the department via the TransAction Portal (https://tap.dor.mt.gov)

All licensees must submit their labeling, packaging, and exit packaging applications and documents by no later than August 1, 2022.

A licensee that fails to submit labeling, packaging, and exit packaging applications for approval by August 1, 2022, shall be subject to disciplinary proceedings.

**When are marijuana and marijuana products required to be in approved labeling and packaging?**

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

A licensee must maintain approval letters for all product labels, product packages, and exit packages at the licensed premises and to make those letters available to the department’s inspectors upon request.

**What about labels and packages that were compliant under the former Montana Medical Marijuana Act?**

To fully implement the new packaging and labeling requirements, all licensees must submit their labeling and packaging applications to the department by August 1, 2022.

Note: Licensees may continue to use packaging and labeling that is compliant with the former Montana Medical Marijuana Act (Title 50, chapter 46, MCA) while awaiting the department’s approval of their applications, provided the applications were submitted by August 1, 2022.
How many labels will need to be submitted? What about generic vs. custom labeling fees?

There are currently four (4) standard marijuana product categories that require labels:

- marijuana flower
- ingestible marijuana-infused products
- non-ingestible marijuana-infused products
- marijuana concentrates and extracts

The four standard labels can be used for sales to both registered cardholders and adult-use consumers. The specific medical marijuana labels are only for marijuana and marijuana products that exceed THC limitations for adult-use consumers found in §16-12-224, MCA. In summary, applicants should not have to submit more than eight (8) total product types for their labels.

Applicants will be given the option of selecting and affirming the use of a generic label for each of the marijuana product categories for both adult use and medical products. The generic template labels will be available for download from the department’s website.

For applicants that choose to submit their own custom label design, they must submit one (1) template label for each marijuana product type for department review and approval (up to a total of 8).

A new label application is not required when the marijuana facts panel information changes for disclosures unless the marijuana or marijuana products are in excess of the THC levels set in §16-12-224, MCA.

Disclosures not requiring a new label application are:

- levels of total potential psychoactive THC, THC, THCa, CBD, or CBDa
- date of harvest, strain name, or ingredients

If the applicant uses the DOR-generic template for a label type, there is no fee for that item, nor will an attachment (photo or accurate rendering) of the label be required.
If the applicant wishes to submit a custom label template, the fee is $25 per label. A photo or accurate rendering of the proposed label must be submitted with the application.

**Generic vs. custom packages: submissions, requirements, and fees:**

An applicant is required to submit at least one package application for each marijuana product type, whether generic or custom, as well as a description of the marijuana product(s) that will be placed in each generic or custom marijuana product package.

**Generic:**

A generic package is, “packaging without any graphic or design elements, including the logo, whether preprinted on the package or affixed later with sticker or by other means.”

If the applicant submits a generic packaging application, there is no fee associated with the packaging application, nor will an attachment of the packaging (photo or accurate rendering) be required.

**Custom:**

A custom marijuana product package means, “a package that contains variations in graphic or design elements, including logos,” from the generic label templates.

**For example:**

Boxes used for pre-rolls with a graphic for “Grape Ape” and a different graphic for “Cherry Pie” would be considered two (2) custom marijuana product packages.

A custom marijuana product package does not mean a package with variations in language, such as product information or instructions, or a package that depicts flavor variation without an accompanying change in graphic or design, or a different size, shape, or color.

**For example:**

Mylar bags used for marijuana flower using different colors to indicate indica, sativa, or hybrid strains. Use of various sized bags would not be considered custom marijuana product packages.
A customized package application is required to include a photo or accurate rendering of the package.

**How many exit package applications need to be submitted? What are the application fees?**

An applicant must submit at least one application for each exit package type it will use. A single exit package application can include multiple, unique exit packages. If the applicant intends to use the same exit package type in multiple sizes or shapes, it may submit the information about each size and shape within the same application.

The application fee is $10 per exit package. Applications are required to include images of the proposed exit packaging and documentation that all exit packaging has been certified as child-resistant by a federally qualified third-party child-resistant package testing firm.

**Exit packaging, requirements & restrictions:**

Marijuana and marijuana products must be placed in resealable, child-resistant exit packaging to protect public health as provided in § 16-12-208, MCA. An exit package is defined as, “a sealed container or package provided at the retail point of sale, in which any marijuana item already within a container is placed.”

Multiple products can be placed in the same exit package at the point of sale. Child-resistant exit packaging must comply with federal child resistance standards and is designed to be significantly difficult for children under 5 years of age to open and not difficult for adults to use properly.

- Per ARM 42.39.102, the standard for child-resistant packaging is set by the federal consumer product safety commission (CPSC) and the testing procedures found in 16 CFR 1700.20 (2012).
- It is required that documentation shall be submitted during the application process that all exit packaging have been certified as child-resistant by a federally qualified third-party child-resistant package testing firm.
Exit packaging must be opaque.

Exit packaging must contain the warnings, verbatim, as required by § 16-12-215, MCA:

- "WARNING: Consumption of marijuana may cause anxiety, agitation, paranoia, psychosis, and cannabinoid hyperemesis."
- "WARNING: Consumption of marijuana by pregnant women may result in fetal injury and low birth weight."
- "WARNING: Consumption of marijuana by nursing mothers may result in infant hyperactivity and poor cognitive function."

**Be sure to ask your exit-packaging supplier for proof (via documentation) that the exit packaging is child-resistant; this will be required as an attachment in the application process.**

**Exit Package Examples:**

![Exit Package Examples](image)

---

**The application process:**

MTRevenue.gov  (406) 444-6900  TDD Montana Relay 711
1. All applicants, whether as an initial license applicant or existing licensee, must apply to the department (on a form provided by the department) for approval of their labeling & packaging of each marijuana product category intended for sale to customers, in addition to an application for exit packages.

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

3. The department shall review each application and then notify an applicant, in writing, whether the label, package, or exit package application has been approved or rejected.

4. Whenever the department denies a submission, a denial reason will be noted, and the applicant will be notified. (Fees will not be assessed). Applications that contain multiple items (e.g. a packaging application with multiple types of packaging) may result in a combination of individual approvals and denials based upon the qualifications of each individual item. The applicant will be required to submit a new application for any individual items that the department denied. The department shall notify the applicant, in writing, of the deficiencies or issues with the application or submitted materials.

**The application fees and payment deadlines:**

- **Generic labels:**
  
  There is no fee associated with the use of generic labels (all fees are assessed as a final step in the approval process), and attachments (photos or accurate renderings) of the proposed labels are not required.

- **Custom labels:**
  
  If the applicant elects to use a custom label, the fee is $25 per label and attachments of photos or accurate renderings are required. All fees are assessed as a final step in the approval process.

- **Generic packages:**
  
  There is no fee associated with the use of generic packages (all fees are assessed as a final step in the approval process), and attachments (photos or accurate renderings) of the proposed packaging are not required.
• **Custom packages:**

If the applicant chooses to use a custom package, the fee is $10 per package and attachments of photos or accurate renderings are required. All fees are assessed as a final step in the approval process.

• **Exit packages:**

Applications are $10 per exit package. A photo or image of the proposed exit package and documentation that all exit packaging has been certified as child-resistant by a federally qualified third-party child-resistant package testing firm are required.

An applicant will receive an invoice for all application fees after the department has reviewed the application. The application is not approved until the fee is paid.

The applicant shall pay all invoiced application fees to the department within ten (10) days of receipt of its invoice. An applicant’s failure to pay all invoiced application fees will result in a denial of the application.

**Approved labeling and packaging:**

A licensee must maintain approval letters for all product labels, packages, and exit packages at the licensed premises and shall make those letters available to the department’s inspectors upon request.

After packaging or labeling has been approved, the approved licensee need not reapply for label, package, or exit package compliance approval if the labeling, packaging, or exit packaging does not change.

**Penalties for false affirmation:**

A licensee that uses non-approved packages, labels, or exit packages shall be subject to disciplinary proceedings.

**Exit packages, requirements, and checklist:**

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes or No</th>
</tr>
</thead>
</table>

MTRevenue.gov (406) 444-6900 TDD Montana Relay 711
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have child-resistant packaging as defined in ARM 42.39.102?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>2. Do you have documentation that all exit packaging has been certified as child-resistant by a federally qualified third-party child-resistant package testing firm?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>3. Is the exit package(s) opaque?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>4. Does the exit package(s) contain the following warnings, as required by § 16-12-215, MCA?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td><em>Statements must be verbatim</em></td>
<td></td>
</tr>
</tbody>
</table>

(1) "WARNING: Consumption of marijuana may cause anxiety, agitation, paranoia, psychosis, and cannabinoid hyperemesis."

(2) "WARNING: Consumption of marijuana by pregnant women may result in fetal injury and low birth weight."

(3) "WARNING: Consumption of marijuana by nursing mothers may result in infant hyperactivity and poor cognitive function."