



CANNABIS
CONTROL
DIVISION
MONTANA

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 thoroughly reading the rules.

The administrative rules for labeling and packaging can be found here, [ARM 42.39.314 to 42.39.322](#). Licensees are required to follow the labeling and packaging rules, and it is their responsibility to know, understand, and operate with respect to 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 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:

- seeds and marijuana plants, [ARM 42.39.322](#)
- 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 and exit requirements for marijuana and marijuana products are found under [ARM 42.39.319 \(2\)\(a\)\(b\)\(c\) & \(4\)](#).

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 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 for marijuana and marijuana products?

- The **label** is the **text (typed information)** printed on or affixed to the product package. It provides information about the marijuana or marijuana product.

Reminder: some packaging has required statements, per the labeling rules, printed on them instead of the label. However, as these are required labeling statements, the package will be part of the label as well.

- The **package or packaging** is the **physical structure** that holds and protects the product. It may contain logos/graphics/photos, or it may be generic (plain).

For example, custom package: a strawberry logo on a package for a strawberry infused, marijuana ingestible.

- 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.

Note: 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 per ARM [42.39.319](#).

Example of label vs. package:



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

The **label** is the printed information that describes the contents of the product.

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; it may contain designs or be generic (plain) in appearance

When may applications be submitted to CCD?

Dispensary licensees must submit their label, package, and exit package applications to CCD for review and approval prior to selling these items to consumers. 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](#).

All licensees must submit their labeling, packaging, and exit packaging applications and receive approval prior to selling those specific marijuana and marijuana products.

A licensee that fails to submit labeling, packaging, and exit packaging applications shall be subject to disciplinary proceedings.

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 (adult- use versus medical use only):

- marijuana flower (any marijuana infused with a concentrate or extract is then considered to be a concentrate/extract product in its entirety).
- ingestible marijuana-infused products
- non-ingestible marijuana-infused products
- marijuana concentrates and extracts

The four (4) standard labels can be used for sales to registered cardholders and four (4) standard labels for 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](#).

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 who 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 Package:

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."

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 must 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 cannot include multiple, unique exit packages. If the applicant intends to use the same exit package type in multiple sizes, they 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 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 package/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 request that your exit-packaging supplier provide proof (via documentation) that the exit packaging is child-resistant; this will be required as an attachment in the application process.***



EXIT PACKAGE SAMPLES

The packaging/labeling/exit packaging application process:

All applicants, whether as an initial license applicant or existing licensee, must apply to the department via [TAP](#) for approval of their labeling & packaging of each marijuana product category intended for sale to customers, in addition to an application for exit packages.

1. 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.
2. 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.

3. Whenever the department denies a submission, a denial reason will be noted, and the applicant will be notified via a letter in [TAP](#). **(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:

- **Standard 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. **Applicants must use the labels on [CCD's website](#) (label templates).**

- **Standard 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.

- **Standard 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.

- **Standard Custom packages:**

If the applicant chooses to use a custom package, the fee is \$10 per distinct package design, 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 invoice 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.

What about wholesale marijuana and marijuana products?

Wholesale marijuana labels and packages will require applications in [TAP](#) by the wholesaler, not the buyer.

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 (all answers must be "Yes"):

<u>Questions:</u>	<u>Yes or No</u>
1. Do you have child-resistant packaging as defined in ARM 42.39.102 ?	Yes No
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?	Yes No
3. Is the exit package(s) opaque?	Yes No
4. Does the exit package(s) contain the following warnings, as required by § 16-12-215 , MCA? (1) "WARNING: Consumption of marijuana may cause anxiety, agitation, paranoia, psychosis, and cannabinoid hyperemesis."	Yes No *Statements must be verbatim

Questions?
Contact CCD Education at: DORCCDEducation@mt.gov