Packaging and Labeling
July 2016 | Jamie Dickinson, OLCC Packaging & Labeling Specialist
Before we begin...

- The information provided today will only be on packaging and labeling. If you have a question regarding something else, call 503-872-5000 or send your question to marijuana@oregon.gov.

- Packaging and labeling rules only cover sales to consumers, patients, and designated primary caregivers. Presentation will not cover licensee-to-licensee sales or transfers.

- **This workshop does not replace reading the rules.**

- **Definitions:**
  - Licensee - a person who holds a license issued by the Oregon Liquor Control Commission (OLCC). Includes Producers, Processors, Wholesalers, Retailers, and Labs.
  
  - Registrant - a person registered with the Oregon Health Authority (OHA). Includes Growers, Processors, and Dispensaries.
Covered Material

► Packaging Rule Overview
  ► Followed by Q & A
► Labeling Rule Overview
  ► Followed by Q & A
► Pre-Approval Application Process
  ► Followed by Q & A
# Rule Overview

<table>
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<th>Type of Rule</th>
<th>Where rule can be found</th>
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<tr>
<td>Packaging Rules</td>
<td>OAR 845-025-7000 to OAR 845-025-7040</td>
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<td>Labeling Rules</td>
<td>OAR 333-007-0010 to OAR 333-007-0100</td>
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<tr>
<td>Pre-Approval Process</td>
<td>OAR 845-025-7060</td>
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</table>

Oregon Liquor Control Commission Rules begin with 845
Oregon Health Authority Rules begin with 333
Packaging
What is a Package?

A package is the immediate container or wrapping in which any marijuana item is contained for ultimate sale to a consumer and includes any outer container or wrapping used in the retail display of any such substance to consumers.
Packaging – General Requirements

Packaging cannot be attractive to minors

- No designs, brands, or names that resemble a product that is marketed towards children
- No designs, brands, symbols, or celebrities typically used to market products to minors
- No cartoons
- No images of minors
Cartoons

- Any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:
  - (1) The use of comically exaggerated features;
  - (2) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or
  - (3) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.
Packaging cannot have any false or misleading statements

- Health claims must be substantiated by scientific evidence
- Cannot use the word “organic” if the product has not been properly certified
- Cannot claim that the product is gluten-free unless the product follows FDA labeling requirements
Packaging – General Requirements

**Packaging must protect the marijuana item**

- Containers and packaging that hold marijuana items must protect those items from contamination and must not expose the marijuana item to any toxic or harmful substance.
Packaging – General Requirements

All marijuana items, except plants and seeds, must be sold in child-resistant packages.

- There are two types of child-resistant packages.

  - Single-use
  - Continually, child-resistant
Child-Resistant Packaging

The type of marijuana item determines the type of child-resistant package.

<table>
<thead>
<tr>
<th>Type of Packaging Required</th>
<th>Resealable &amp; Continually, Child-Resistant Package</th>
<th>Child-Resistant when Product Leaves Store (Single Use)</th>
<th>Child-Resistant Packaging Not Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Marijuana Item Sold</strong></td>
<td>Multiple-servings of: Edibles Topicals Tinctures Concentrates and Extracts</td>
<td>Usable Marijuana Single-servings of: Edibles Topicals Tinctures Concentrates and Extracts</td>
<td>Plants Seeds</td>
</tr>
</tbody>
</table>

Child-Resistant Packaging

- A child-resistant package is a package that has been tested by a qualified, third-party testing firm and determined by that firm to meet the standards listed in 16 CFR 1700.

- The package must be designed or constructed to be significantly difficult for children under 5 years of age to open and not difficult for adults to use properly.

Consumer Product Safety Commission

§ 1700.15 Poison prevention packaging standards.

To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, the Commission has determined that packaging designed and constructed to meet the following standards shall be regarded as "special packaging" within the meaning of section 2(4) of the act. Specific application of these standards to substances requiring special packaging is in accordance with §1700.14.

(a) General requirements. The special packaging must continue to function
Child-Resistant Packaging

In order for a package to be approved as child-resistant, the licensee or registrant must provide the OLCC with documentation that the package was tested and met the standard.

- Ask your manufacturer for proof of child-resistance.

Example of Child-Resistant Test Results
Exit Packaging

- An exit package is defined as “a sealed container provided at the retail point of sale in which any marijuana items already within a container are placed.”
- Exit packages can be used to add child resistance to a container that is not child resistant on its own.
- Multiple products can be placed in the same exit package at the point of sale.
- Exit packages may also be reused as long as they are re-sealable and remain child resistant throughout the life of the product. Old labels must be removed.
Exit Packaging

- Pursuant to OAR 333-007-0090, all exit packaging must contain a label that reads: "Keep out of the reach of children" in at least 8 point Times New Roman, Helvetica, or Arial font.

- All exit packages must be approved by the OLCC Pre-approval Process. The fee for approval is $100 per package.
  - If exit package contains only the required warning without any additional text, graphics, pictures or logos, it will be considered generic and will not need label approval.

- The exit package may be provided by company that produced or packaged the marijuana item or the retail store or dispensary where the marijuana item will be sold.
Retailer / Dispensary Responsibility

- The retailer or dispensary is responsible for making sure that products that require a child-resistant exit package leave the store in one.
  - If the container holding the marijuana item is child resistant and on the OLCC approved list, it does not need an exit package.
  - If the item is not in a child-resistant package, the retailer or dispensary is responsible for making sure that the marijuana item leaves in an OLCC-approved exit package.
Reuse of Packaging

- Only packaging that is re-sealable and continually child-resistant may be re-used.
  - The old label or labels must be removed, and the package must have a new label or labels attached to it.
- Any re-used packaging cannot contaminate the marijuana items and must not expose the item to any toxic or deleterious substances.
Questions about Packaging Rules?
Labeling
What is a Label?

- A label is any written, printed, or graphic matter affixed to, applied to, attached to, blown into, formed, molded into, embossed on, or appearing upon or adjacent to a package containing a marijuana item for purposes of branding, identifying, or giving any information with respect to the item or to the contents of the package.
Labeling – General Requirements

Each marijuana product type has specific requirements that must be included on the label.

- OAR 333-007-0010 through 333-007-0100
- All requirements outlined in the rules must be listed on the label.
- Failure to include any required information may result in denial of the label application.
333-007-0030
Marijuana Plant Labeling Requirements
Prior to a marijuana plant being sold or transferred to a consumer, patient or designated primary caregiver a tag or label must be affixed to the plant or plant container that has the following information:

1. Producer’s business or trade name and licensee or registrant number;
2. Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;
3. Name of the strain; and
4. Universal symbol
Labeling – General Requirements

All required information on the label must:

- Be in at least 8 point Times New Roman, Helvetica or Arial font, although the font can be larger;
- Be in English, but the information can be included in other languages; and
- Be unobstructed and conspicuous, meaning that all required information must be visible on the outside of the package.
- Include all laboratories, batch testing numbers, and dates tested.
- Be unobstructed and conspicuous.

Additionally, if the marijuana item falls into more than one category that item must comply with the labeling requirements for both categories.
Labeling – General Requirements

A label may:

- Have additional information on the label that is not required by rule. This information can be in any size or font.
- Have more than one label panel on a package.
Every label must contain:

- A principal display panel;
- The universal symbol; and
- All required information outlined in the labeling rules.

The universal symbol must be at least 0.48 inches wide by 0.35 inches tall.
The principal display panel is the part of a label that is most likely to be displayed, or seen when on display for sale.

Three things must appear on PDP (except for plants):

- Product Identity
- Universal Symbol
- Net Weight
  - US Customary and SI Units
  - Bottom 30% of package
Label Prohibitions

- A label may not:
  - Contain any untruthful or misleading statements, including incorrectly using the term "organic" or making an unsubstantiated health claim; or
  - Be attractive to minors:
    - No designs, brands, or names that resemble a product that is marketed towards children
    - No designs, brands, symbols, or celebrities typically used to market products to minors
    - No cartoons
    - No images of minors
Small Containers

- If the container is too small to fit all of the required label information, only the following information on the container label in at least 8 point Arial, Helvetica, or Times New Roman font:
  - Principal display panel that includes the net weight, universal symbol, and product identity;
  - Licensee or registrant business or trade name and licensee or registrant number;
  - For licensees, UID number and for registrants, batch or process lot number;
  - Concentration of THC and CBD; and
  - Required Warnings

- The remaining required information must be included on an outer package or on a leaflet or hangtag that accompanies the marijuana item.

- If an outer package is used, all required information must be on the outer container, even if some of the information is already included on the inner container.
Activation Time

- Activation time is the amount of time it is likely to take for an individual to begin to feel the effects of ingesting or inhaling a marijuana item.
  - Activation time may be expressed in words or through a pictogram.
  - If a user will begin to feel the effects right away, the activation time can be listed as immediate.
  - If the product has a delayed reaction, the licensee or registrant can determine what the activation time is for their particular product.
Medical Grade Symbol

- The medical grade symbol is a symbol that is used by licensees that produce cannabinoid products, concentrates, or extracts that have a THC concentration that is above the recreational concentration limit.
  - For use by OLCC licensees at OLCC licensed retail stores.
  - Products can only be sold to a patient or designated primary caregiver.
  - Licensees who want to produce medical grade products must follow the requirements set out in OAR 845-025-3300, as well as the rest of the rules.

The medical grade symbol must appear on the principal display panel and be at least 0.35 inches in diameter.
Additional Edible Labeling

- For cannabinoid edibles, it is required that the following information be placed on the label:
  - List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid edible.
  - The amount, in grams, of sodium, sugar, carbohydrates and total fat per serving.
    - A licensee or registrant must have documentation that demonstrates the validity of the calculation and must make that documentation available upon request.
  - If the edible is perishable, a statement that the edible must be refrigerated or kept frozen. If the edible is not perishable, no statement is needed.
  - List of potential major food allergens.
Allergens

- A licensee or registrant must list major food allergens on the label if the edible contains:
  - Milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans as an ingredient, or
  - Any ingredient that contains protein derived from: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans.

- Licensees and registrants must label major food allergens in one of two ways:
  - Include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients whenever the name of the food source of the major allergen does not appear elsewhere in the ingredient statement.
  - Use the word "Contains" followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in a font size that is the same font size used for the list of ingredients.
False and Misleading Statements

- **Organic**
  - Must be certified by a qualified certifying agent
  - Even if certified, still restrictions on how term is used.
  - Contact the Oregon Department of Agriculture for specific information

- **Gluten-Free**
  - Must follow specific guidelines to label product as gluten-free

- **Health Claims**
  - Claims that the product cures or prevents a disease are prohibited
  - Health claims must be substantiated by scientific evidence
Products Derived from Industrial Hemp, ORS 571.300

- Products derived from industrial hemp may be sold in OLCC retail locations if they are packaged, labeled, and tested in accordance with the rules.

- Labeling Differences:
  - The warning for a hemp label can be altered to say "For use by adults 21 and older. Keep out of reach of children."
  - The "BE CAUTIOUS" warning is also not required for edible products made from products derived from industrial hemp.

- Products derived from industrial hemp cannot be sold in medical dispensaries.
In addition to the packaging and labeling rules, both the OHA and OLCC prohibit the sale or transfer of marijuana items that are likely to appeal to minors because of its shape, design, or flavor. This includes:

- Products modeled after non-cannabis products primarily consumed by and marketed to children;
- Products in the shape of an animal, vehicle, person or character;
- Products made by applying cannabinoid concentrates or extracts to commercially available candy or snack food items; or
- Products that contain dimethyl sulfoxide (DMSO).

Additionally, a processor may not add any substance that would increase potency, toxicity, or addictive potential, or create an unsafe combination with other psychoactive substances.

- The prohibited additives include, but are not limited to, nicotine, caffeine, or chemicals that increase carcinogenicity.
- Cannabinoid products may be added to an item that has naturally occurring caffeine (such as coffee or chocolate), but cannabinoid products cannot be added to an item that contains artificial or added caffeine (such as a caffeinated soda or energy drink).
What changed in the labeling rules?

- FDA Warning: “This product is not approved by the FDA to treat, cure, or prevent any disease”
- Small Containers
- Exit Package warning: “Keep out of the reach of children”
- Medical Grade Symbol for licensees
- Concentration Limits

### Recreational THC Concentration

<table>
<thead>
<tr>
<th>Marijuana Item Type</th>
<th>Maximum THC per serving</th>
<th>Maximum THC per container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edibles</td>
<td>5 mg</td>
<td>50 mg</td>
</tr>
<tr>
<td>Topicals</td>
<td>N/A</td>
<td>6%</td>
</tr>
<tr>
<td>Tinctures</td>
<td>N/A</td>
<td>1,000 mg</td>
</tr>
<tr>
<td>Capsules</td>
<td>10 mg</td>
<td>100 mg</td>
</tr>
<tr>
<td>Concentrates or Extracts</td>
<td>N/A</td>
<td>1,000 mg</td>
</tr>
</tbody>
</table>

### Medical THC Concentration

<table>
<thead>
<tr>
<th>Marijuana Item Type</th>
<th>Maximum THC per serving</th>
<th>Maximum THC per container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edibles</td>
<td>N/A</td>
<td>100 mg</td>
</tr>
<tr>
<td>Topicals</td>
<td>N/A</td>
<td>6%</td>
</tr>
<tr>
<td>Tinctures</td>
<td>N/A</td>
<td>4,000 mg</td>
</tr>
<tr>
<td>Capsules</td>
<td>100 mg</td>
<td>4,000 mg</td>
</tr>
<tr>
<td>Suppositories</td>
<td>100 mg</td>
<td>4,000 mg</td>
</tr>
<tr>
<td>Transdermal Patches</td>
<td>100 mg</td>
<td>4,000 mg</td>
</tr>
<tr>
<td>Concentrates or Extracts</td>
<td>N/A</td>
<td>4,000 mg</td>
</tr>
</tbody>
</table>
Questions about Labeling?
Pre-Approval Process
Pre-Approval Process

The OLCC reviews marijuana packages and labels that are for ultimate sale to a consumer, patient, or designated primary caregiver.

- **Timelines**
  - Medical Registrants: packages and labels must be approved by October 1, 2016. Only items with approved packages and labels may be transferred by a dispensary after October 1, 2016.
  - OLCC Licensees: packages and labels must be approved before selling any product to a consumer.
Preparing to apply

Only licensees, registrants, and individuals in the process of applying for a license or medical registration can apply for package and label approval. Approval will not be given until the applicant has an active OLCC license or medical registration.

**OLCC Licensees**
- Must apply for an OLCC license
  - Business details
  - Funding Sources
  - Land Use Compatibility Statement
  - Business Operating Plan
  - Floor Plan
  - Proof of right to occupy premises
  - Other documentation depending on license type.
  - See OLCC rules and Business Readiness Guide for more information.

**Medical Registrants**
- Must be registered with OHA – contact the OHA for more information
- Must provide some business information to OLCC:
  - Business Name
  - Address
  - Contact Information
  - Registration Number
Application Checklist

Application is online and allows applicants to pay with a credit card.

Packaging
- $100 application fee per package
- Documentation showing package has been certified for child resistance by third-party testing firm
- Clear photographs of all sides of package
- Photograph and description of item to be sold in package
- Dimensions of package
- Color and size variations of package

Labeling
- $100 application fee for each label approved
- Clear photographs depicting all label panels and the correct scale
- Photograph and description of item that corresponds with label
- Color and flavor variations of label
Packaging Application Review

- Once you have submitted a complete application and paid the application fee, the OLCC will review the application to determine whether:
  - Has been certified as child resistant by a qualified third party child-resistant package testing firm;
  - Is not marketed in a manner attractive to minors;
  - Does not contain any untruthful or misleading content;
  - Contains a marijuana item that is compliant with ORS 475B, OAR 333 Divisions 7 and 8, or OLCC marijuana rules.
Once you have submitted a complete application and paid the application fee, the OLCC will review the application to determine whether the label:

- Is in at least 8 point Times New Roman, Helvetica or Arial font;
- Is unobstructed and conspicuous, meaning that all required information must be visible on the outside of the package.
- Has a principal display panel
- Has a universal symbol that is at least the minimum size;
- Complies with the OHA’s labeling rules, OAR 333-007-0010 to 333-007-0100.
Application Fee

Application Fee is $100 per package AND $100 per label.

- The application fee for packaging and labeling is **NON-REFUNDABLE**.
  - Will not be refunded even if you are denied a license or registration.
  - Will not be refunded if your package or label application is denied.
  - Will not be refunded if you decide to withdraw your license application.
  - Will not be refunded if you submit an application for packaging that has already been approved.
Process

- If the application is approved, the applicant will receive notice that the application was approved.

- If there is a problem with the package or label application, the OLCC will notify the applicant via email and outline the specific problems or deficiencies with the application.
  - The applicant will have 30 days to correct the deficiencies and resubmit. No additional fee is needed to resubmit.

- If the resubmitted application did not fix all deficiencies, the application will be denied and the applicant will have to submit a new application and fee.

- If the package is not approved because it is not child-resistant, the applicant can either: (1) fix the package to make it child-resistant, or (2) notify the OLCC that an exit package will be used.
Approved Packages

- Once the OLCC begins to approve packages, the list of approved packages will be published on the OLCC website.
- Once a package is on the approved list, a licensee or registrant may use it without seeking additional packaging approval.
Generic Labels

- A generic label is a label that contains only the required information outlined in the rule and contains no graphics, pictures, or logos.
  - A generic label must have the universal symbol
- Generic labels do not need to be submitted to the OLCC for approval.
Using the Online System

If you have already applied for a recreational license, you don’t need to create a new account.

If you are a medical registrant or applying for a new recreational license, you will need to register for a business account.
Registering for an Account

- Email will be the primary form of communication. When you register, you will receive an activation link that must be clicked on within 24 hours.

- Log in at least once every 30 days or your account will become inactive.

- Remember your password and security questions.
  If you forget, it may cause a delay in you being able to access your account.
After signing in, this is the page that will appear.

To apply for package and label approval, click the “Packaging/Labels” tab.

<table>
<thead>
<tr>
<th>Type</th>
<th>Location</th>
<th>Record ID</th>
<th>Status</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recreational Processor</td>
<td>Tax Map ID: 6217-00-00312</td>
<td>1000087648F</td>
<td>Pending License Payment</td>
<td>$ Pay for License</td>
</tr>
<tr>
<td>Laboratory</td>
<td>9078 SE McLoughlin Blvd, Milwaukee, 97222</td>
<td>1008673445</td>
<td>Pending License Payment</td>
<td>$ Pay for License</td>
</tr>
<tr>
<td>Research Certificate</td>
<td>9078 SE McLoughlin Blvd, Milwaukee, 97222</td>
<td>10000866680</td>
<td>Pending License Payment</td>
<td>$ Pay for License</td>
</tr>
<tr>
<td>Recreational Wholesaler</td>
<td>1234 Wholesale St, Oregon City, 97265</td>
<td>1001219625</td>
<td>Pending License Payment</td>
<td>$ Pay for License</td>
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<td>Recreational Wholesaler</td>
<td>1234 Wholesale St, Oregon City, 97265</td>
<td>1001248937</td>
<td>Pending License Payment</td>
<td>$ Pay for License</td>
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<tr>
<td>Recreational Wholesaler</td>
<td>1234 Wholesale St, Oregon City, 97265</td>
<td>1001244684</td>
<td>Pending License Payment</td>
<td>$ Pay for License</td>
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<td>10012772AF5</td>
<td>Pending License Payment</td>
<td>$ Pay for License</td>
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<tr>
<td>Recreational Producer</td>
<td>as seen, 606055</td>
<td>1000062547A</td>
<td>New</td>
<td>Details</td>
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<tr>
<td>Recreational Producer</td>
<td>123 Falke St, Portland, 95555</td>
<td>1000660EF5E</td>
<td>New</td>
<td>Details</td>
</tr>
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<td>Recreational Producer</td>
<td>9078 SE McLoughlin Blvd, Milwaukee, 97222</td>
<td>100076892B8</td>
<td>New</td>
<td>Details</td>
</tr>
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<td>Recreational Producer</td>
<td>123 Falke St #111-111-111, Portland, 95555</td>
<td>100121054A7</td>
<td>New</td>
<td>Details</td>
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<td>Recreational Producer</td>
<td>123 Falke St, Portland, 95555</td>
<td>10013812359</td>
<td>New</td>
<td>Details</td>
</tr>
<tr>
<td>Recreational Producer</td>
<td>9078 SE McLoughlin Blvd, Milwaukee, 97222</td>
<td>1000625465ECC</td>
<td>Active</td>
<td>Details</td>
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<td>Recreational Producer</td>
<td>9078 SE McLoughlin Blvd, Milwaukee, 97222</td>
<td>100062738D1</td>
<td>Active</td>
<td>Details</td>
</tr>
</tbody>
</table>
Packaging/Labeling Tab

- This screen shows you all package and label applications and the current status of those applications.
- To apply for new packaging, click the “+Add Packaging” button.
- Each package must have a separate application.
Add Packaging Tab

**Package Title**
Name your package application.

**Package Description**
This description will appear on the Dashboard.

**Package Types**
Use the drop down menu to select the category that best describes your package.

**Package Material**
The material that your package is primarily made of.

**Packaged Item Description**
Describe the product that is being sold in the package.

**License associated with Package**
Provide the license that will produce or package the product.

**Type of Packaged Item**
Type in the type of item that will be sold in the package.
Child-Resistant Packaging

Check the box indicating whether the package has been certified as child-resistant.

- If the package has been certified as child-resistant, select the type of closing mechanism.
- You must also submit documentation proving the package has been tested and certified.
Size Variations

**Type in the physical dimensions or size of your package.**

The dimensions can be in inches, fluid ounces, grams, or by count.

If you have a package in multiple sizes, add all variations here.
Color Variations

Type in the color variations for the package only.

Adding color variations can mean:

1. Adding the colors of a package with multiple colors

2. Adding the color variations of the same package that comes in different colors.
Photographs of Package

- On this screen, upload photographs of your package. Photographs should:
  - Show all sides of the package
  - Show all color and size variations of the package.
To begin a Label Application, click “+ Add Label.”

After you save your application, you will be directed back to the dashboard. Here, you can review and pay for the application. The application is not submitted until the application fee is paid.
Label Application

Title
Name your label application.

Type of Product
Use the drop down menu to select the category that best describes the product that corresponds with the label.

Description
This description will appear on the Dashboard.

License or Registration
Licensee or registrant number that is processing or packaging the product.
**Color and Flavor Variations**

*Type in any color or flavors, if applicable. If not, click “Continue” at bottom.*

- Labels that are the same, except for variations in color and flavor, can be listed on the same application.
- Type in the color and flavor variations in the appropriate box.
Labeling Photographs

- Upload images of all label panels.
  - Images should include a measurement device or scale.
  - If the label has color or flavor variations, photographs of all variant's label panels should also be included.
- Photographs must be clear, readable, and in focus.
After you save your application, you will be directed back to the dashboard. Here, you can review and pay for the application. The application is not submitted until the application fee is paid.
Acknowledgement

- Before submitting payment and completing your application, you must acknowledge that all the information provided is complete and true.
Questions about the Pre-approval Process or Application?