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GUIDANCE ON PRODUCT LABELING & PRODUCT REGISTRATION

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Introduction

This guidance summarizes regulatory requirements pertaining to product characteristics, packaging, and labeling. Its intended audience is cannabis establishments pursuing product registration.

Appendix A offers a pre-registration checklist. Appendix B illustrates testing requirements.

This guidance explains how the Cannabis Control Board (CCB or "the Board") interprets relevant laws and rules. Citations are provided where appropriate. This guidance is intended as a helpful reference for cannabis establishments. It is not a comprehensive exposition of regulatory requirements, and it does not amend or supersede the laws and rules it addresses. Readers should consult <u>7 V.S.A. Chapter</u> 33 and Board Rule 2 for useful background.

Product Registration

Vermont law requires that all cannabis and cannabis products offered for sale to consumers be registered with the Board based on compliance with regulatory requirements.

Except bulk flower and bulk pre-rolls, retailers may purchase only cannabis and cannabis products that carry active registrations. Retailers have a duty to affirmatively verify product registration status. The responsibility to obtain a registration rests with the licensee that places the product into the final form encountered by the consumer.

Purpose

Pre-market registration of products is the cornerstone of Vermont's regulated cannabis marketplace. Registration ensures that products comply with statutory health requirements and that consumers can be confident in the integrity of regulated cannabis.

The Board understands that timely, consistent product registration is important to the vitality and fairness of Vermont's regulated cannabis marketplace. To make best use of product registration, an establishment should:

- + Be familiar with laws, rules, and guidance governing product packaging.
- + Assess a product's compliance thoroughly before submitting it for registration.
- + Compare product prototypes and labels directly to governing laws, rules, and guidance, not to similar products once seen on the market.
- + Be sure required test results accompany submissions. See separate guidance on testing.
- + Avoid waste by confirming compliance before investing in packaging and labeling.
- + Submit for registration only products intended for sale upon approval. The product registration system is not an efficient (or binding) way to test hypotheticals and borderline products. Incomplete registration submissions cannot be used to "hold" positions for products in development.

For product questions, email ccb.products@vermont.gov.

Product registrants have an independent duty to verify and maintain the regulatory compliance of their products. In the rare event a non-compliant product is registered in error, the registration may be cancelled. Error does not entitle a non-compliant product or others like it to remain on the market.

What to Expect While Registering

Please allow 15 to 30 days for processing. Resubmitted registrations will be given priority. Registration agents may request clarification by email or phone.

Status Explanations

A registration submission may be assigned one of the following statuses:

•	Draft	Not in queue for registration staff	
•	Submitted	Submitted by licensee and in queue for registration staff	
•	Incomplete	Elements need corrections noted in "incomplete reasons" sec	

Incomplete Elements need corrections noted in "incomplete reasons" section
 Resubmitted Submitted by licensee and in priority que for registration staff

• **Registered** Actively registered and approved for consumer sale

Who May Register

A product may be registered only by an actively licensed cannabis establishment associated with its manufacturing or branding.

Naming Registration Submissions

A product name submitted to the registration portal should accurately represent the product by size, flavor, weight, count, THC concentration, and if applicable, extraction method.

When Distinct Registration is Required

Unique product registrations are required as follows:

- **General Guidelines** Product registration must be obtained for each unique combination of weight, servings, THC concentration, and flavor/strain/blend. Multiple packaging formats can be included in a single product registration. Multiple product types in separate packaging cannot be combined into a single package.
- Flower/Pre Rolls All sizes and formats of a single cultivar grown by a single cultivator can be grouped into a single product registration. All formats intended for consumers must be included. Multipacks require a separate registration that accurately depicts the exact count and size of each cultivar.
- **Bulk Flower / Bulk Pre-Rolls (retailers only)** Bulk flower and pre-roll options for retailers need only one registration per product type, *e.g.*, bulk flower and/or bulk pre rolls. Bulk flower and pre rolls cannot be merged into a single registration.
- Clones A single product registration is needed for each regardless of cultivar
- Concentrates Unique registration is required for each size, strain mix, blend, type, or grade.
- Vapes Unique registration is required for each size, strain, and concentrate type.
- **Edibles/Tinctures** Unique registration is required for each size, count, and flavor. Multipacks require a separate registration that accurately depicts the exact count and size of each flavor.

• **Topicals** — Unique registration is required for each size, count and formula.

Examples

- → Chocolate bars with multiple flavors must be registered separately.
- → Variations on serving size—*e.g.*, 2.5mg and 5mg—must be registered separately.
- → Variations on servings per package--e.g., 5 vs 10—must be registered separately.

Where to Find Warning and Symbol Files

Vector files and raster files of required warning symbols, as well as files illustrating compliant use of the mandatory health information warning, are available from the Board's website.

Establishment-to-Establishment Packaging

When products are transferred from one licensee to another within the supply chain, packaging must include the required warning label and symbols, and content must be clearly identified. For example, the packaging must say the common name of the item, such as flower, tincture, butter, or oil. Further, the package must be labeled with the required symbols as prescribed by Rule 2.2.10. In anticipation of planned rule amendments, licensees may use ASTM-standard coloring in the "CONTAINS THC" symbol on the left below:



Symbol Size and Color for Intra-Supply Chain Packaging:

For all packaging, the symbols must be at least .5" X .5". The required colors are as follows:

Black: (CMYK) 0,0,0,100 Red: (CMYK) 0,95,100,0 Red: (Pantone) PMS 485

All establishment-to-establishment packaging must:

	Prominently display the required warning symbols discussed above (and prescribed in 2.2.10(b)) Identify its contents (<i>e.g.</i> , flower, oil, butter, tincture, etc.)
	Be free from false or misleading statements and therapeutic claims
	Not appeal to persons under 21
Cultiva	tor packaging bound for other licensees must additionally:
	Include the name and license number of the cultivator
	Include the strain, variety, and potency of the cannabis contained in the package
	Include a produced-on date (see details below)
	Include the weight of cannabis, and associated harvest lot and process lot numbers.

Consumer Packaging

Child-deterrent vs. Child-resistant Packaging

Cannabis offered for sale to consumers must be packaged in *child-deterrent* packaging. Refer to the definition at 7 V.S.A. § 861(16).

Cannabis products that are for sale to a consumer must be packaged in *child-resistant*, opaque packaging. Refer to the definition at 7 V.S.A. § 861(17).

Plastic Packaging Prohibited

Plastic packaging is prohibited. Rule 2.2.9(b). The Board has waived the plastic prohibition for certain gaskets, seals, and other applications necessary to achieve compliance with requirements bearing on health, safety, or child-deterrence.

Consumer Package Labeling

Label Content

All cannabis and cannabis products packaged for sale to consumers must include the specific warning labels required by Rule 2.2.10. Text, italics, bolding, and all-caps lettering should be reproduced verbatim. Each of the following four criteria must be included as their own individual element

1. Health Information Warning:

Consumer packaging must display the following health information warning:

Cannabis has not been analyzed or approved by the Food and Drug Administration (FDA). For use by individuals 21 years of age and older or registered qualifying patient only. **KEEP THIS PRODUCT AWAY FROM CHILDREN AND PETS. DO NOT USE IF PREGNANT OR BREASTFEEDING.**

Possession or use of cannabis may carry significant legal penalties in some jurisdictions and under federal law. It may not be transported outside of the state of Vermont. The effects of edible cannabis may be delayed by two hours or more. Cannabis may be habit forming and can impair concentration, coordination, and judgment. Persons 25 years and younger may be more likely to experience harm to the developing brain.

It is against the law to drive or operate machinery when under the influence of this product. National Poison Control Center 1-800-222-1222.

This warning may be printed in 10-point font Times New Roman, Helvetica, Ariel, or another font size easily readable by the average consumer.

Warnings must be on the outermost part of the consumer packaging, sometimes called marketing-level packaging, except that warnings of adequate font size may be printed to the interior of a durable peel-away label that is easily discovered by the consumer. In cases of layered packaging, the warning must be visible on the product as it will be encountered by a consumer at retail and as it will be stored by the consumer.

The health warning should be affixed to the package in a manner likely to stay with the package for the duration of its use.

2. Child Access Warning

Consumer packaging must include the following general warning label, including capitalization in at least 10pt font in bolded Times New Roman, Helvetica, or Ariel:

KEEP OUT OF REACH OF CHILDREN

This warning must be prominently displayed on the packaging. It cannot be under a peel-away label or attached with a tag. Consumers must be able to read this label on the outermost, marketing-level layer of packaging.

3. Warning Symbols

The following warning symbols must also appear on all consumer packaging. These symbols must be prominently displayed, clear, and readable by the average consumer. They may not be covered or hidden by branding or artwork on the packaging in any way. They must appear in color, size and content exactly as required by Rule 2.2.10.



Symbol Size and Color for General Packaging:

For all packaging the symbols must be at least .5" X .5" The required colors are as follows:

Black: (CMYK) 0,0,0,100 Red: (CMYK) 0,95,100,0 Red: (Pantone) PMS 485

4. Multiple Serving Warning

Finally, products for oral ingestion that contain multiple servings must have the following warning label in at least 10pt font in bolded Times New Roman, Helvetica, or Ariel:

INCLUDES MULTIPLE SERVINGS

This warning must be prominently displayed on the packaging. It cannot be under a peel away or attached with a tag. Consumers must be able to read this label at the outermost, marketing-level layer of packaging.

The symbol must be 25% of the serving's height and width for edible packaging but not less than .25" X .25" for items packaged as a single serving. For example, edibles are separately wrapped in single servings within an outer layer of packaging.

Consumer Packaging Requirements by Product Type

Cannabis Flower

Cannabis flower packaging for retail sale must:

	Include Include Include Include	y its contents (e.g., flower, shake) the name and license number of the cultivator the strain, variety, weight and potency of the cannabis contained in the package a produced-on date (see details below) a web address or QR code that links to the test results of the content product packaged process lot number
Pre-ro under	State lav	olls d with any form of concentrated cannabis, except sifted kief, are "cannabis products" v. Infused pre-rolls therefore should comply with the above requirements for ower packaging, but also must
	Specify	kaged in opaque, child-resistant packaging a date of manufacture, the date the product was infused and packaged tely list all ingredients and additives
	abis Prod bis produ	lucts uct packaging for retail sale must:
	For not	y the content (e.g., flower, oil, butter, cookie, water, salve) In flower cannabis products intended for ingestion/inhalation: Identify the number of 5 milligram or less servings in the package up to a maximum of 100 milligrams per package. Exempt for concentrate/vape Accurately list all ingredients and additives contained in the product Ensure that the 5 milligram or less servings are easy for consumers to measure, either by clear and visible markings on the product or by physical separation of the servings. Identify the produced-on date (see details below) Include manufacturer name and license Include a "best if used by date," the date by which potency and freshness cannot be assumed Except inhaled products with immediate effect, include a statement about the length of time it typically takes for the product to take effect Include a web address or QR code that links to the test results of the content product packaged Include manufacture lot Include any other relevant requirements for labeling food outlined by the Department of Health for edible or drinkable food products Inducts not intended or readily used for ingestion or inhalation:
	For pro	State conspicuously that the product is for topical application only List all ingredients used in production Warn of common irritants or allergens Include process lot, meaning whole or partial harvest lots that follow different paths/processes toward market

Understanding Required Elements

To reduce ambiguity and promote consistency in labeling, the Board understands the following label elements as described below.

Produced-on Date

For cultivators, the produced-on date is the date harvested cannabis flower from a given harvest lot was fit for packaging.

For manufacturers, the produced-on date is the date a manufactured product was finished and fit for sealing in a container for sale to consumers.

In the case of smokable flower products, such as conventional and infused pre-rolls, the produced-on date is the produced-on date assigned by the cultivator.

The produced-on date serves to give the consumer an accurate and non-misleading understanding of the relative freshness of a product. The date may not be artificially advanced by deferring packaging of finished product or repackaging product. If it is appropriate to advise consumers of a reasoned shelf life, a best-by date may be provided in addition to a produced-on date.

Lots

A "lot" describes cannabis or cannabis products grown or produced at the same time, under the same fundamental conditions, and through the same fundamental processes. The concept serves to ensure that certificates of analysis are representative of the products to which they are assigned, as well as to ensure traceability in case of adulteration or adverse reactions.

"Harvest lot' means cannabis grown in the same manner. To meet the criteria for a single harvest lot, the given lot of cannabis would need to be on the same flowering, fertilizer, and pesticide application schedule. A single harvest lot may contain one or multiple cultivars of cannabis." Rule 2.1.3(g).

"Process lot' means whole or partial harvest lots that follow different paths toward market or diverted into waste. For example, a single harvest lot would be broken into two process lots if half was sold fresh frozen to a manufacturer, and half was dried, cured, and sold as bulk flower to a retailer. Rule 2.1.3(r).

In cases of ambiguity, a practical test of whether two products may be regarded as from the same lot is: Is there a reasonable possibility that the content, composition, and characteristics of any two products differ, other than by cultivar grown in the same harvest lot? If the answer is "no," the products generally may be regarded as from the same lot.

Ingredients & Additives

A label must accurately inform the consumer of all ingredients and additives found in a cannabis product.

An ingredient is any discrete food or baking product, such as flour, gelatin, high fructose corn syrup, or sodium bicarbonate.

An additive is any other substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristic of a cannabis product (including any substance intended for use in producing,

manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding the product).

Additives include extracts of foods and plants that are not used in conventional home food preparation, substances added to alter the characteristics of a product, and substances used to flavor or color a food base. For example, a manufactured mushroom extract must be listed as an additive, rather than represented as a conventional food ingredient.

For guidance concerning the permissibility of additives, see "Additives," at p.13, supra.

Label Characteristics

Appeal to Persons Under 21

Product marketing, labeling, and form may not have special appeal to youth or persons under 21 years of age, including by featuring "objects, such as toys, inflatables, movie characters, cartoon characters, child-friendly depictions of food or other consumables, or include any other display, depiction, or image designed in any manner likely to be appealing to minors or anyone under 21 years of age." CCB Rule 2.2.9.

Applicable standards are substantially the same for products as for advertising. Refer to the Board's Advertising Guidance, at pp. 8-9.

False or Misleading Content and Therapeutic Claims

Packaging and labeling must not contain false or misleading statements, therapeutic claims, or any statement that contradicts or conflicts with the content of the health information warning.

Applicable standards are substantially the same for products as for advertising. Refer to the Board's Advertising guidance, at p. 8.

Use of "Organic"

USDA does not certify cannabis as organic due to the product's federal legal status. Consequently, a cannabis product label cannot represent that the product is "organic." See 7 CFR Part 205.

A small number of cannabis establishments have corporate names or assumed business names that contain variants of "organic." Those establishments should take care not to feature their names on a label in a manner that would suggest to a reasonable consumer that their product itself is organic. The CCB may require that a label include a clarifying statement.

Mimicry and Infringement

Product labeling and form must not infringe the intellectual property rights of another or mimic famous-brand foodstuffs. Infringement may mislead the consumer as to the manufacturer of a product and the source of its ingredients, and it may enhance the risk that a cannabis product is mistaken for a non-cannabis food product. Infringement also may create civil liability to intellectual property holders.

Product Characteristics

Product Form

Manufacturers should take special care to avoid product forms that are inherently child-attractive or dangerously easy for unaware persons, including children, to confuse for non-cannabis foodstuffs. Although cannabis-infused confections are permitted, the Board will not register products with characteristics that make them inherently appealing to children or especially prone to confusion with food. Examples include lollipops and suckers, candy beads, and variations on famous-brand candies and snacks favored by children.

Flower Concentration not to Exceed 30% THC

THC concentration in cannabis flower may not exceed 30%. 7 V.S.A. § 868(a)(1).

Cannabis Product Concentration not to Exceed 60% THC

THC concentration in solid and liquid cannabis products may not exceed 60%. 7 V.S.A. § 868(b)(1). Concentrate sealed in non-refillable vape carts may exceed this limit. *Id.* § 868(b)(2).

Package Content not to exceed 100mg THC

A single package of consumable cannabis product may not contain more than 100mg THC. § 7 V.S.A. 881(a)(3)(A). Solid concentrates, oils, and tinctures may exceed this limit. *Id*.

5mg Servings & Easy Measurement

The Board is required by 7 V.S.A. § 881(a)(3)(B) to ensure "that cannabis products are labeled in a manner that states the number of servings of tetrahydrocannabinol in the product, measured in servings of a maximum of five milligrams per serving." Related Board rules require that "servings must be easy for a consumer to measure, either by clear and visible marking on the Cannabis Product or physical separation of servings." Rule 2.6.3(b)(iv)(1).

"Serving" is defined within the regulatory prohibition on hemp-derived intoxicating products at Rule 2.17.2(c): "the amount reasonably ingested by a typical consumer in a single instance." Consequently, consistent and realistic serving enforcement is important not only to effectuate the 5mg concentration limit imposed by the General Assembly, but also to prevent unregulated sale of dangerous, intoxicating hemp-derived products.

FDA regulations define "serving" in a manner consistent with Rule 2.17.2(c): "an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food." 21 CFR 101.9 (b)(1). The serving size proposed in a product offered for registration should conform to FDA serving references.

Serving & Measurement Guidelines

To effectuate fair and consistent application of 7 V.S.A. § 881(a)(3)(B) and Rule 2.6.3(b)(iv)(1) in a manner implements the intent of the General Assembly, the following serving-and-measurement principles are applied to products offered for registration:

→ A product may not be registered with improbable or unrealistically small serving sizes.

- → For pills and gummies, one discrete unit is a serving. Consumers do not consistently separate pills and gummies according to score lines.
- → Cannabis beverages must be packaged in sealed containers no larger than 16 ounces.
- → 12-16oz beverages bay be assigned no more than two servings.
- → A cannabis product must be physically separated in sealed compartments, each containing no more than 5mg THC, or accompanied by scoring or another mode of serving demarcation that most consumers (1) can use easily and reliably, and (2) consistently do use in real-world applications to apportion servings of no more than 5mg.
- → If a manufacturer proposes a product in packaging or a form that appears to the Board not to comply with measurement standards, it is the burden of the manufacturer to credibly demonstrate real-world consumer behavior consistent with its claims, not the burden of the product registration staff to disprove that behavior. However, compliance with Rule 2.6.3(b)(iv)(1) is presumed for:
 - A tincture packaged with a dropper that can be used to reliably meter doses of not more than 5mg THC, based on dropper demarcations (i.e., "drops" may not be used as a dosing unit), or
 - A 12-16 ounce beverage that a consumer may divide into equal parts, each containing no more than 5mg THC.
 - A single-serving beverage of fewer than 12 ounces, containing not more than 5mg THC.

Final Form

In order to demonstrate compliance with 7 V.S.A. § 881(a)(3)(B) (the 5mg/serving limit) and Rule 2.6.3(b)(iv)(1) (the easy-measurement rule), a product offered for registration must be in the final form intended for consumption or must come into that form through a predictable, repeatable preparatory method consumers credibly will follow in the real world (e.g., by brewing a 5mg tea bag or stirring a single sachet into 12oz of water).

A "final form" policy also is necessary to effectuate the General Assembly's intent with regard to child-resistant packaging and warning labels. Consumers tend to keep packaged cannabis and cannabis products in original packaging, stored in nightstands, medicine, cabinets, and other places where children and visitors don't go. Homemade cannabis foodstuffs will bear no label and will tend to be kept near food in refrigerators and kitchens. For these reasons, THC additives, precursors, and baking ingredients are not eligible for registration.

Additives

Additives to a cannabis product must not adulterate the product as defined by CCB Rule 2.1.3(a).

Except for direct derivatives of the plant *Cannabis sativa L.*, all additives to consumable products must be Generally Recognized as Safe by the United States Food and Drug Administration. Rule 2.6.4(a).

Additives to inhalable products must comply with Board schedules of allowed and disallowed ingredients. Rule 2.6.4(b).

Terpenes

"The total terpene content of a cannabis product intended for inhalation or vaporized formulation may not exceed 10 percent by weight." Rule 2.6.4(c). The limit may be waived if a manufacturer can show additives were not used. *Id*.

"Any concentrated terpenes added to a cannabis product shall be disclosed on the label." Id.

Hemp Flower

Hemp flower may not be blended with cannabis flower in an inhalable cannabis product. The introduction of hemp flower to cannabis flower is incompatible with the seed-to-sale traceability required by 7 V.S.A. § 881(a)(1)(J) and misleads consumers, who will assume flower was grown by a licensed cultivator under regulated conditions.

Caffeine

Additive caffeine enhances the potency and cardiovascular effects of cannabis and is prohibited as an adulterant. Caffeine intrinsic to a food base—for example, naturally brewed coffee in a beverage or espresso powder in a chocolate grenache—is permitted so long as caffeine thus introduced does not exceed 200mg/serving.

Alcohol and Nicotine

Cannabis products may not contain alcohol or nicotine. 7 V.S.A. § 868(a)(3).

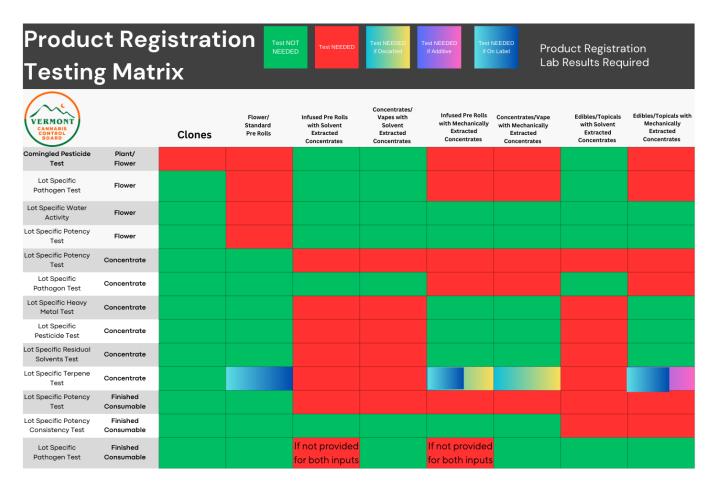
Flavoring

Characterizing flavors, including herbal flavors, are prohibited in inhalable cannabis products but permitted in ingestible cannabis products if Generally Recognized as Safe. 7 V.S.A. § 868(a)(2).

Appendix A: Product Registration Checklist

Characteristic	Source
If orally ingested, any additives are GRAS.	2.6.4(1)
Additives and substances do not enhance potency or addictiveness.	7 V.S.A. § 881(a)(1)(I)
Additives, substances, and packaging do not enhance appeal to persons <21 yoa.	7 V.S.A. § 868 & 881(a)(1)(I)
Additives and substances are not toxic.	7 V.S.A. § 881(a)(1)(I)
Additives and substances are not misleading.	7 V.S.A. § 881(a)(1)(I)
Additives and substances do not promote overconsumption.	7 V.S.A. § 864
Additives and substances do not suggest curative or therapeutic effect.	7 V.S.A. § 864
If inhalable, is free of characterizing flavor not naturally occurring in cannabis.	7 V.S.A. § 868
Is free of nicotine and alcohol.	7 V.S.A. § 868
If flower, THC concentration NMT 30%.	7 V.S.A. § 868
If inhalable, ingredients conform to schedule of those approved/disapproved in guidance.	2.6.4(2)
If inhalable, terpenes are NMT 10% by weight, unless shown by to be naturally occurring without addition of concentrates.	2.6.4(3)
If concentrate, NMT 60% THC, except sealed, non-consumer-fillable vape cart.	7 V.S.A. § 868
Contains no meat or dairy product. (NB: Baked products containing dairy are not dairy products.)	2.2.4(e)-(f)
Does not require time or temp control for safety.	2.2.4(g)
If appropriate, satisfactory documentation of pH and Water Activity (Aw).	2.2.4(h)
If appropriate due to biological concerns, satisfactory documentation of process authority review.	2.2.4(i)
Produced, packed, and stored in sanitary conditions and protected from potential contamination.	2.1.3(a)
Tests within tolerances set by testing guidance.	2.1.3(a)
Strength, quality, purity, and content consistent with labeling and consumer expectation.	2.1.3(a)
Free of substances that may increase potency, toxicity, carcinogenicity, or otherwise enhance health risk.	2.1.3(a)
Is free of synthetic cannabinoids, to include delta-8 and delta-10 THC.	2.17.1; 2.1.3(a)
If a product, does not exceed single-transaction limit of one ounce or equivalent.	7 V.S.A. § 907(b)
If a product, NMT 100mg THC/package, or is an exempt topical, solid concentrate, oil, or tincture.	7 V.S.A. § 881
If a product, label states number of servings, each serving NMT 5mg, or is an exempt topical.	7 V.S.A. § 881(a)(3)(B)
If a product, is offered in finished form with individual servings "easy for a consumer to measure, either by clear and visible markings on the cannabis product or physical separation of servings."	2.6.3(b)
Packaging free of misleading statements	2.2.9(a)
Packaging clearly identifies contents	2.2.9(a)
Packaging is not plastic, or is waived	2.2.9(b)
Packaging features mandated warning labels: (1) box warning, (2) warning symbol, (3) keep out of reach of children, and if applicable, (4) multiple-serving warning.	2.2.10
If foodstuff, committee is satisfied with pH and water activity parameters	2.2.4(h)
If foodstuff, committee believes process authority review is unnecessary, or if necessary, is satisfactory	2.2.4(1)

Appendix B: Product Registration Testing Matrix



^{*}If Mechanically Extracted Concentrate is produced in the same facilitity, only pathogen test needed on final concentrate