



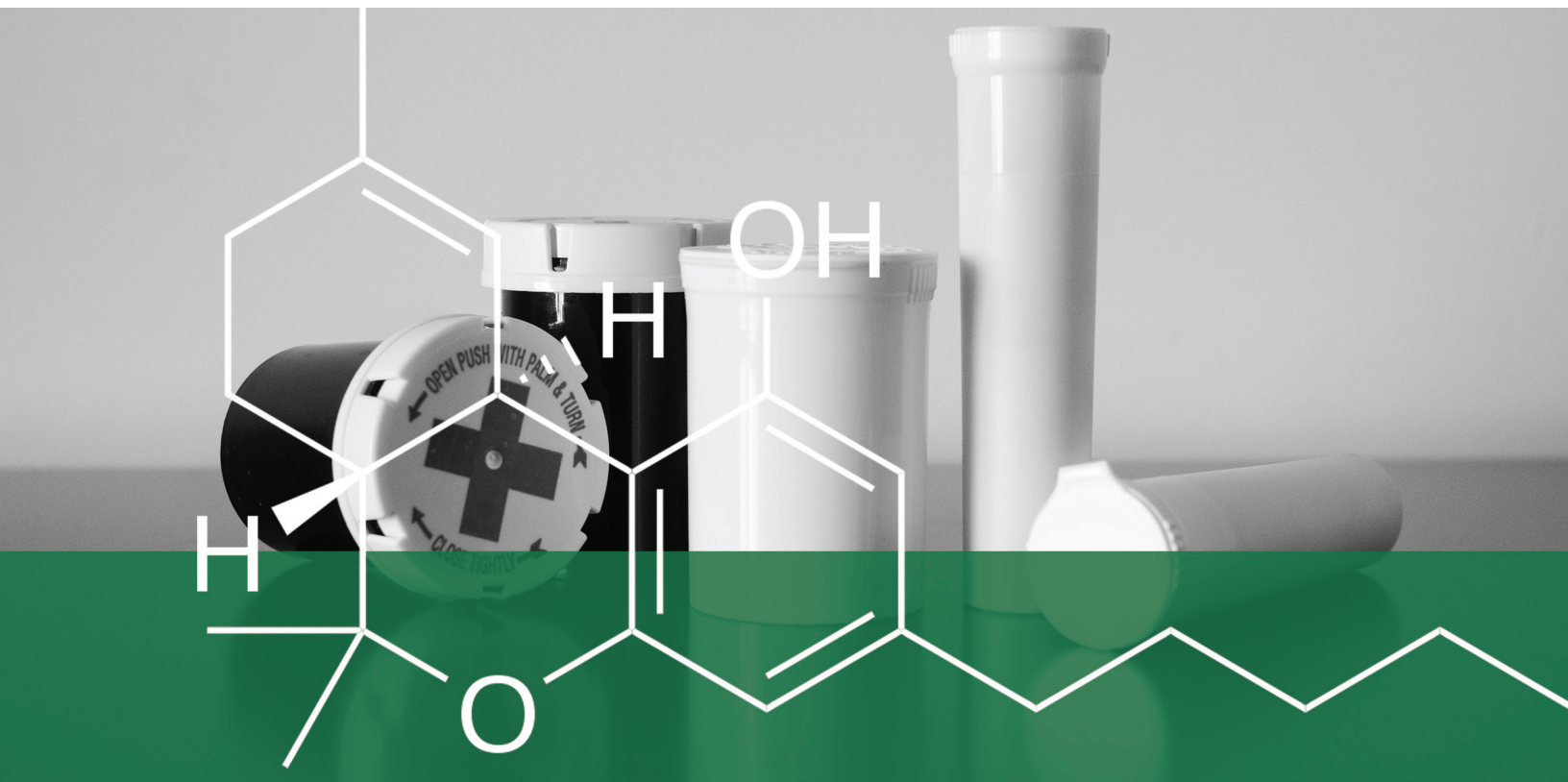
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CANNABIS

PACKAGING AND LABELING: RECOMMENDATIONS FOR SENSIBLE AND CONSISTENT REGULATIONS ACROSS STATES AND NATIONS



An update of a paper that was previously released by the Council on
Responsible Cannabis Regulation and produced in collaboration with the
National Cannabis Industry Association

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INTRODUCTION

BACKGROUND

Legal cannabis has become a majority phenomenon in the U.S. At present, medical cannabis use is legal in 33 states and D.C. and ten states and D.C. allow cannabis for adult use. Despite this major shift in state policy, cannabis remains a Schedule I substance at the federal level and its production and distribution is unlawful in the absence of a DEA license. At the same time, there has been a détente of sorts between the federal government and states with laws authorizing cannabis-related activity. In August 2013, the Department of Justice issued the “Cole Memorandum,”¹ which explained that the Department would not target individuals acting in compliance with state law, as long as their conduct did not interfere with eight specific federal law enforcement priorities, such as preventing revenues from going to criminal enterprises and preventing the diversion of cannabis to other states. Although then-Attorney General Jeff Sessions rescinded this memorandum in January 2018, US Attorneys appear to have maintained the de-prioritization of state-regulated and state-compliant cannabis activity.

Given the state-based nature of the evolution of cannabis laws, licensed commercial cannabis businesses operate in accordance with relatively stringent regulations which vary substantially from state to state. There is a tendency for new cannabis regulatory agencies to modify and expand upon the frameworks enacted by early adopters, which is beneficial in that the states are making use of the practical experience of others while still functioning as “laboratories of democracy,”² but is detrimental in other regards.

This paper presents regulatory recommendations and model regulations that emerged from a critical assessment of sub-optimal and inconsistent state regulations in one specific area: cannabis packaging and labeling. The decision to explore cannabis packaging and labeling was inspired by the great patchwork of inconsistent packaging and labeling rules across legal cannabis states, which have been the subject of much debate and frustration among industry and consumers alike. The overarching goal is to encourage greater consistency and judiciousness in cannabis rulemaking by providing state regulators with model packaging and labeling regulations supported by in-depth research, analysis, and input from diverse stakeholders and experts.

PROCESS AND PARTICIPANTS

In late 2015, the Council on Responsible Cannabis Regulation (CRCR), which has since ceased to operate, and the National Cannabis Industry Association (NCIA) joined forces on a project designed to address the need for best practices and greater consistency in state regulation of cannabis packaging and labeling. The central goal was to generate detailed regulatory recommendations for cannabis packaging and labeling for state regulators based on feedback from a diverse working group of subject-matter experts, stakeholder surveys and input, as well as examining federal standards for similar products and lessons from legal cannabis states.

¹<https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>

²New State Ice Co. v. Liebmann, 285 U.S. 262 (1932)

THE NATIONAL PACKAGING AND LABELING STANDARDS COMMITTEE

The recommendations for the regulation of cannabis packaging and labeling presented in this white paper were initially developed over the course of a year by the multi-disciplinary National Packaging and Labeling Standards Committee (“Committee”). The Committee was comprised of cannabis industry and ancillary business leaders, legal professionals specializing in cannabis and other hyper-regulated industries, researchers, public health experts, and state cannabis regulators participating on an ex-officio basis. CRCR and NCIA representatives served as Committee co-chairs and supervised the project. The members of the Committee and their affiliations at the time of the working group meetings are listed below.

Jaime Lewis (Co-Chair)

Mountain Medicine, National Cannabis Industry Association

Jordan Wellington (Co-Chair)

Vicente Sederberg, Council on Responsible Cannabis Regulation

Chloe Grossman

Council on Responsible Cannabis Regulation

Tim Moxey

Botanica Seattle

Chris Van Gundy

Keller and Heckman LLP

Sabrina Fendrick

Berkeley Patients Group

Kayvan Khalatbari

Denver Relief Consulting, Cresco Labs

Kristi Knoblich

Kiva Confections

Jill Lamoureux

Trellis Research Group, BOTECH

Mike LeBlanc

Compliant Packaging

Ross Kirsh

Quark Distribution

Miren Klein (Ex-Officio)

California Department of Public Health

David McNicoll

Dave’s Space Cakes, Oregon Responsible Edibles Council

Andrew Livingston

Vicente Sederberg, Council on Responsible Cannabis Regulation

Paul Mullaly

LabelTec

Kristin Nevedal

Americans for Safe Access

Amy Poinsett

MJ Freeway

Mary Shapiro

Mary L. Shapiro Law

Lindsay Short

Zoots

Lindsay Topping

Dixie Elixirs

Jane Wilson

American Herbal Products Association

Shannon Wilson

Mahatma Concentrates

Kristi Wolff

Kelley Drye & Warren LLP

Jodi Duke, MPH, CPH

CU School of Medicine, Colorado School of Public Health, CORE

We would like to specifically recognize Chloe Grossman, Jordan Wellington, and Andrew Livingston (all listed), who were the primary authors of the 2015 document.

In the fall of 2018, members of NCIA's Packaging and Labeling Committee reviewed the original document in order to see whether any modifications to the recommendations would be appropriate. Encouragingly, nearly all of what was originally written stood the test of time. We would like to thank the following members of the Packaging and Labeling Committee for their participation in this review and for their ongoing service to NCIA:

Karen Bernsteing (Chair)
Bernstein IP

Eden Irgens
Range

Brian Smith (Vice Chair)
Talking Trees Farms

Carl Rowley
Thompson Coburn LLP

Alex Berger
Emerge Law Group

Tammy Sagastume
Quake Scientific Products

Mauria Betts
Potency Branding

Nancy Warner (Immediate Past Chair)
Assurpack LLC

Lisa Hansen
Plaid Cannabiz Marketing

Azia Weisz
Green Rush Packaging

OBJECTIVES

The Committee's work was guided by the following objectives:³

- ▶ To ensure cannabis packaging and labeling regulations protect public and consumer health and safety.
- ▶ To ensure cannabis packaging and labeling regulations have a sound legal and empirical basis.
- ▶ To identify packaging and labeling requirements for cannabis that are effective and operable, while recommending the elimination of those that are not.
- ▶ To align state cannabis packaging and labeling regulations with federal laws and regulations for packaging and labeling of products with shared characteristics (e.g., food products, drugs, dietary supplements, cosmetics, alcoholic beverages, tobacco products), when appropriate.
- ▶ To encourage uniformity in state cannabis packaging and labeling regulations.

PROCESS IN BRIEF

The project began with four Committee meetings in which members discussed existing state cannabis packaging and labeling requirements. Each early discussion was guided by an extensive list of existing state requirements ("conceptual draft") circulated a week in advance. Committee members had the opportunity to provide verbal input during meetings and were encouraged to submit written comments as well, which many did.

³ Loosely based on the Organisation for Economic Co-operation and Development's (OECD) conceptualization of good regulation, as described in the OECD Guiding Principles for Regulatory Quality and Performance. Retrieved from: <https://www.oecd.org/fr/reformereg/34976533.pdf>

After eliminating items universally believed to be ineffective or inoperable, the Committee reviewed the remaining content and identified topics to be included in a survey sent to members of NCIA, which is comprised of cannabis and ancillary businesses. The complete survey was sent to NCIA's membership in May 2016. A total of 178 individuals participated, with 121 of the participants completing the entire survey. The survey findings are referenced throughout this white paper.

The survey findings for each packaging or labeling provision under consideration were summarized and circulated to the Committee in advance of an in-person meeting at the NCIA Cannabis Business Summit in June 2016. During this meeting, the Committee reviewed the survey findings and finalized recommendations for several topics where the survey and initial Committee positions did not create consensus. The CRCR team then spent months reviewing hundreds of pages of meeting notes, written comments, and survey findings, conducting additional research and examining external resources to synthesize the information collected into a draft white paper. After a draft was circulated and feedback from the Committee obtained, CRCR finalized this white paper with the intent to present its findings to interested policy makers.

WHITE PAPER OVERVIEW

This white paper provides a complete set of regulatory recommendations for cannabis packaging and labeling developed by the multi-disciplinary stakeholder Committee. The paper is structured so that each recommendation is followed by a discussion of the logical basis for that position, including support from the survey, federal legal research, and in-depth policy discussions. Following the recommendations, the paper provides model packaging and labeling regulations, intended for use by lawmakers and regulators in legal cannabis states, and an appendix containing discussion of state THC potency limits.

Disclaimers: The views, opinions, findings, and recommendations expressed in this paper do not necessarily reflect the views or opinions of any individual who contributed to its development. Rather, the positions put forth in this paper emerged from a consensus-driven process and therefore reflect the views and opinions of the majority of participants as interpreted and elaborated by cannabis policy experts at CRCR and NCIA. NCIA, the individual members of the National Cannabis Packaging and Labeling Standards Committee, and the individual members of NCIA's Packaging and Labeling Committee take no responsibility for any errors or omissions in the information contained in this paper. The regulatory recommendations contained in this paper are intended to apply to finished cannabis products packaged and labeled for sale to a consumer that were produced by state-licensed, registered, or otherwise approved commercial cannabis businesses that operate within a comprehensive state regulatory framework for commercial cannabis activity. The packaging and labeling regulations and recommendations presented in this paper are not intended to apply to industrial hemp producers, industrial hemp products produced by industrial hemp producers, or products created therefrom by any entity other than a state-licensed or otherwise authorized commercial cannabis business. The packaging and labeling regulations and recommendations presented in this paper are exclusively applicable to cannabis products packaged and labeled for sale and should not be interpreted to apply to in-process cannabis products, cannabis products in shipping containers, or laboratory samples of cannabis products. In non-vertically integrated environments, critical labeling information may need to be shared with producers and retailers; regulators can either impose specific labeling requirements on shipping containers, as implemented in Colorado, or allow businesses to resolve this issue amongst themselves.

CANNABIS LABELING REGULATORY RECOMMENDATIONS

RECOMMENDATION #1

FONT AND TYPE SIZE

All required labeling information shall be in any legible font that is at least 1/16th of an inch height based on the lower case letter “o.”

This is a basic FDA requirement for the principal display of a variety of products, including packaged food products.⁴ FDA regulations are quite specific about the size and appearance of text on packages and labels, but we believe

at present the most critical appearance-related item for cannabis products is preventing use of a font that is illegible or so small that required label information is difficult to read for normal adults.

RECOMMENDATION #2

COMMON OR USUAL NAME OF THE PRODUCT

Common or usual name of the product in boldface type on all cannabis product labels. “Cannabis” should be included.

Under FDA regulation, a statement of identity is required on the labeling of all food products⁵, botanical supplements⁶, over-the-counter medicines⁷, and prescription drugs.⁸ The common or usual name of a food or supplement product serves as the statement of identity if a product’s name is not established in federal law or regulation.⁹ In the absence of federally-established cannabis product names, we recommend requiring that common or usual name be included in cannabis product labeling. Just as dietary supplements must have the term “dietary supplement” or a similar term on their labeling, we recommend requiring that cannabis product labeling include the term “cannabis.”¹⁰

Policymakers may leave the meaning of “common or usual name” open to licensee interpretation or establish guidelines for proper product identification. At present, most states that regulate cannabis do not have guidelines in place for proper cannabis product identification, but we

see no harm in advancing consistent terminology. Guidelines may limit the labeled name of cannabis products to their generic product category, like “cannabis concentrate” or “ingestible cannabis-infused product;” a term describing the product type, like “cannabis wax” or “cannabis transdermal patch;” or some combination of both, like “cannabis-infused carbonated beverage” or “cannabis concentrate: shatter.”

When guidelines for common or usual name are written into regulation, regulators should keep in mind that cultivators are likely to include strain (e.g., blue dream) and variant (e.g. sativa, indica, hybrid) voluntarily to differentiate their products as these factors drive many consumers’ purchase decisions. Furthermore, the same strain may vary greatly across licensees for a variety of reasons and there is no way to police strain name usage at present. As such, strain and variant labeling could be promoted as a voluntary best practice but should not be required by regulation.

⁴ 21 C.F.R. § 101.2(c)

⁵ 21 C.F.R. § 101.3(a)

⁶ *ibid.*

⁷ 21 C.F.R. § 201.61(a)

⁸ 21 C.F.R. § 201.50(a)

⁹ 21 C.F.R. § 101.3(b)

¹⁰ 21 C.F.R. § 101.3(g)

RECOMMENDATION #3

LICENSEE NAME AND PHONE NUMBER OR EMAIL ADDRESS

Name and business phone number or email address of the licensee that produced the finished product for the purpose of receiving product complaints and inquiries.

Members of the Committee originally disagreed on how licensee information should be provided and whether it should be required at all. Some Committee members believed licensee name and contact information should be mandatory on all product labels, while others recommended mandatory inclusion of a web address where contact information is made available. There was also a group that believed licensee information is unnecessary on product labeling because it is captured in the unique identifying code required for traceability (see Recommendation 5) and because manufacturers and dispensaries often use branded packaging.

We ultimately chose to recommend mandating that all cannabis product labels include the name and business phone number or email address of the licensee that produced the finished product for two reasons.

First, federal law mandates that a business name and address be placed on labeling for packaged food and dietary supplements, tobacco products, drugs, cosmetics, and alcoholic beverages.¹¹ As previously noted, one of our primary goals is federal alignment wherever possible. The major

difference between what we are proposing and what is standard in federal regulation is that we substituted business phone number or email address for business address because publicizing cultivation and manufacturing site addresses presents unnecessary security risks.¹²

Second, readily available licensee contact information will make it easier for cannabis consumers to make product-related inquiries and complaints. Consumers won't have access to the electronic tracking systems used by licensees and regulators, so the unique identification code on a product label alone does not provide the information needed for consumers to promptly inform licensees of product concerns. It is clearly inappropriate for consumers to contact federal agencies about a federally illicit product and the state and local bodies that handle product-related issues are often limited in scope and resources, so we believe providing a phone number or email address for consumers to directly contact the producer or retailer is the best option. Cannabis regulators can control licensee response to consumer contact by establishing rules for complaint recordkeeping, investigation, and reporting.

RECOMMENDATION #4

NET QUANTITY OF CONTENTS

Net quantity of contents on all cannabis product labels:

- ▶ *Stated in both U.S. customary and Metric (SI) units;*
- ▶ *Expressed as fluid measure if the product is a liquid; and*
- ▶ *Expressed as weight if the product is solid, semi-solid, or viscous.*

Net quantity of contents represents the total weight or volume of a finished product, excluding packaging, and is federally mandated on labels

for food and dietary supplements, drugs, and alcohol.¹³ Under FDA regulations, the net quantity of contents for a given product is its net weight

¹¹ Food and Dietary Supplements: 21 C.F.R. § 101.5; Tobacco products: 21 U.S.C. § 387c(a)(2); Drugs: 21 C.F.R. § 201.1; Cosmetics: 21 C.F.R. § 701.12; Distilled Spirits: 27 C.F.R. § 5.36

¹² A member of the Committee suggested an alternative to the recommendation presented in this paper in the interest of aligning completely with federal requirements for other products. Under this alternative scheme, business address could be required on all cannabis product labels but regulations would specifically authorize P.O. Box addresses to give licensees a way to limit risk associated with address disclosure.

RECOMMENDATION #4 (Continued)

if the product is solid, semi-solid, or viscous, or its net contents if the product is a liquid. As such, “net quantity of contents” or “net contents” better captures appropriate measurement for a range of products than “net weight,” which is commonly used in cannabis regulations at present.

The net quantity of contents for packaged solid, semi-solid, and viscous cannabis products should be expressed in dry weight, and preceded by the phrase “Net Weight,” the abbreviation “Nt. Wt.” or simply “Net.” For all packaged liquid cannabis products, net quantity of contents should be expressed in fluid measure and preceded by “Net Contents” or “Net.” FDA regulations authorize net quantity of contents to be expressed in weight, fluid measure, or a combination of count and

weight or measure [e.g., Net Weight: 2 oz. (56.7 g) (10 cookies)] and we see no issue with allowing the same for multi-unit cannabis products.¹⁴

Cannabis products are sometimes measured in U.S. Customary Units (e.g. ounce, fluid ounce) and other times in the International System of Units (“SI units,” e.g., gram, milliliter). The Fair Packaging and Labeling Act (FPLA), as amended in 1992, requires use of both, so we recommend requiring that net quantity of contents be displayed in both U.S. Customary Units and SI Units. For example, net contents for a cannabis-infused beverage should be stated in both fluid ounces and milliliters, while net weight for flower should be in ounces or pounds and grams.

RECOMMENDATION #5

LICENSE NUMBER AND BATCH OR LOT CODE

Require all cannabis product labels to include the license number of the cultivator or manufacturer who produced the finished product and the product batch or lot code, for tracking purposes.

Identification of cannabis products is a critical component of product tracking. At present, legal cannabis states lack uniform requirements for cannabis product identifiers, so the codes licensees use to identify products vary from state to state and sometimes across licensees in the same state. This patchwork has the potential to create significant issues in the future when cannabis may lawfully enter interstate commerce, so it is important to begin advancing industry-wide consistency now.

The Committee and industry participants who completed our survey overwhelmingly supported development of an industry-wide standardized format for product identifiers. Participants generally agreed that requiring multiple identifying codes (e.g., all lots of cannabis used to produce a lot of concentrate) is a waste of limited label space. This information is not useful to consumers and is not needed in

printed form because the information is available electronically through the seed-to-sale tracking system (mandatory in nearly all cannabis states). There was broad support for a more efficient alternative: a single identifying code, comprised of a distinctive combination of letters and numbers, that provides electronic access to the complete history of the production and distribution of the batch or lot. Cannabis businesses would need interoperable traceability systems in order to share data electronically through identifying codes. Industry-wide identification standards would also be necessary, as they are the common language that makes interoperability possible.

The Committee explored various existing and new standard identification models, including a reworking of the National Drug Code, but was unable to reach consensus on format and content. The group identified four potential key components of a cannabis product identifying

¹³ Food and Dietary Supplements: 21 C.F.R. § 101.105(a); Prescription Drugs: 21 C.F.R. § 201.51(a); Over-The-Counter Drugs: 21 C.F.R. § 201.62(a); Wine: 27 C.F.R. § 4.32(b)(2); Distilled Spirits: 27 C.F.R. § 5.32(a)(4); Malt Beverages: 27 C.F.R. § 7.22(a)(4)

¹⁴ 21 C.F.R. § 101.7(a)

RECOMMENDATION #5 (Continued)

code – licensee, product type, packaging lot, and production lot/batch – but not all participants felt all four components were necessary. There were further disagreements about the number of digits necessary to uniquely identify each batch or lot of finished cannabis product due to the fact that the cannabis industry is growing rapidly and still faces many unknowns as a new industry subject to conflicting federal and state laws.

Until an industry-wide solution can be reached, we recommend that state regulations require that all cannabis product sold at retail bear labeling that includes the state license or registration number of the cultivator or manufacturer who produced the finished product and a number or code identifying the lot or batch. The license or registration number will be state-issued but the lot or batch code may be assigned by the manufacturer or cultivator in accordance with internal policies and procedures.

More research is needed to support identification

of an appropriate industry-wide identification standard. Cannabis businesses and subject-matter experts, like existing standards development organizations and companies that assign universal identifying codes, should work together to ensure technical and practical matters are contemplated in the ultimate design.

Finally, we are in favor of requiring each cannabis product sold at retail to bear a barcode that is both human- and machine-readable. However, we recommend waiting to require a barcode until after an industry-wide standard for identification is developed because the code specifications should drive barcode format selection. alcohol.¹³ Under FDA regulations, the net quantity of contents for a given product is its net weight if the product is solid, semi-solid, or viscous, or its net contents if the product is a liquid. As such, “net quantity of contents” or “net contents” better captures appropriate measurement for a range of products than “net weight,” which is commonly used in cannabis regulations at present.

RECOMMENDATION #6

INGREDIENTS LIST

Require ingredients listed by common or usual name in descending order of predominance by weight on the label for all cannabis-infused products and concentrates containing at least one ingredient not derived from cannabis.

FDA regulations require an ingredients disclosure on labeling for packaged foods, dietary supplements, drugs, and cosmetics.^{15, 16, 17} The Committee’s general position is that cannabis labeling regulations should require listing of all ingredients, including cannabis, regardless of product type. Modeling after FDA regulations, we support exempting substances that are present in a product at insignificant levels and do not have any technical or functional effect from ingredient labeling.¹⁸ For cannabis, this means processing solvents and cultivation inputs would not be considered ingredients if mandatory pesticide residue, foreign matter, and residual

solvent tests confirm their amounts do not exceed levels considered significant by the state. With this exception, ingredient labeling would not be appropriate for cannabis flower and concentrates containing only substances naturally occurring in cannabis and therefore should not be required for these products.

When an ingredients list is required, cannabis should be included in that list and the part of the cannabis plant or the form (e.g., flower, trim, concentrate) should be identified in parentheses following the word “cannabis.” This is in accordance with FDA requirements for

¹⁵ Food and dietary supplements - 21 C.F.R. § 101.4

¹⁶ 21 C.F.R. § 201.10

¹⁷ 21 C.F.R. § 701.3

¹⁸ 21 C.F.R. § 101.100(a)(3)

RECOMMENDATION #6 (Continued)

identification of botanical ingredients.¹⁹

We recommend requiring ingredients listed by a common or usual name in descending order of predominance by weight on the label for ingestible infused products, non-ingestible infused products, and concentrates containing at least one ingredient not derived from cannabis.

These requirements are similar to those for FDA-regulated food products and dietary supplements. The survey population and Committee strongly support ingredient labeling for these product types, except that the survey population was not asked about ingredients labeling for concentrates because the subject was not considered until after survey circulation.

RECOMMENDATION #7

ALLERGEN LABELING

Require labeling of major food allergens for all ingestible infused products and concentrates that are intended to be cooked with, eaten, or otherwise swallowed and digested (i.e., Activated Concentrates).

We recommend mandating major allergen labeling in accordance with Section 203(a)(1)-(4) of the Food Allergen Labeling and Consumer Protection Act of 2004²⁰ (FALCPA) for all retail packages of cannabis ingestible infused products and cannabis concentrates that are intended to be taken orally, including concentrates that may be used in cooking. Cannabis flower, non-ingestible infused products, and concentrates intended to be smoked or vaporized only should not be subject to this requirement, just as food allergen labeling is not required for raw agricultural commodities, cosmetics, and e-cigarettes.

This would mean requiring that ingestible infused product and concentrate (as applicable) labels declare the presence of major food allergens in plain language. The major food allergens are

milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans and any ingredient containing a protein derived from these foods.²¹ The specific type of tree nut (e.g., walnuts, pecans, almonds), Crustacean shellfish (e.g., lobster, shrimp, crab), and fish (e.g., salmon, flounder, cod) must be declared in allergen labeling. Cannabis products that contain at least one major allergen may be labeled to comply in two ways. The first is to include “Contains” and a list of all major food allergens immediately after or adjacent to the ingredients list. For example, “Contains Milk, Wheat, Egg, and Walnuts.” The second is to place the name of the major allergen in parentheses after the common or usual name of the ingredient that is derived from or contains the major allergen in the ingredients list. For example, “Ingredients: Flour (Wheat), Water, Albumin (Egg)...” and so forth.

RECOMMENDATION #8

NUTRITION FACTS

Require Nutrition Facts on labels for edible cannabis-infused products and concentrates that are intended to be taken orally.

The “Nutrition Facts” panel is common labeling item that contains the quantitative amount per serving (or, as suggested in this section, per unit or container) and percent Daily Value of calories, fat, cholesterol, sodium, carbohydrates, protein,

and certain vitamins in a packaged food product.²² As a result of detailed federal regulations, the appearance and content is consistent across states and now recognizable to most, if not all, U.S. adults.

¹⁹ 21 C.F.R. § 101.4(h)(1)

²⁰ Pub. L. 108-282, Title II

²¹ 21 U.S.C. 321(qq)

²² 21 C.F.R. § 101.9; see 21 C.F.R. § 101.9(c) for specific information about each nutrient

RECOMMENDATION #8 (Continued)

This familiar labeling item has made its way into cannabis regulation but is applied inconsistently. Depending on the state in which a cannabis product is produced, nutritional labeling may not be required, may be required only for products in food or drink form, or may be required for all infused products regardless of ingestion method. Despite this inconsistency, more than three-quarters of our geographically diverse survey population thought nutrition facts should be mandatory for ingestible cannabis products. A subsequent Committee review of federal nutrition labeling laws revealed that, if ingestible cannabis products were treated like equivalent federally-regulated products not containing cannabis, only ingestible products in food or beverage form (i.e., edible cannabis-infused products) would have to include nutrition facts on their labels. This makes sense given the lack of nutritional value, both in terms of quantity and availability to the body, of cannabis-infused tablets, suppositories, tinctures,

and the remaining ingestible products that are not in edible form.

In line with the federal approach, we recommend requiring that each edible cannabis-infused product label include a nutrition facts panel with the content and format specified in 21 C.F.R. § 101.9(c) and (d), except that manufacturer-specified unit (more information detailed in Recommendation 9) should be substituted for serving size. We suggest requiring the same for cannabis concentrates that are intended to be taken orally, including concentrates like cannabis-infused butter that are intended for use in cooking, to align with federal nutrition labeling requirements for cooking fats. The appearance and content of a Nutrition Facts panel on cannabis product labeling should be consistent with FDA standards, except that manufacturer-specified unit should replace serving size.

RECOMMENDATION #9

CANNABIS FACTS PANEL

Require a Cannabis Facts (Potency) panel on all cannabis product labels that includes:

- ▶ *The percentage concentration of Effective THC and all other marketed cannabinoids weight by weight if the product is flower;*
- ▶ *The percentage concentration of Effective THC and all other marketed cannabinoids weight by weight or weight by volume if the product is a non-activated concentrate;*
- ▶ *The milligram content of Active THC and all other marketed cannabinoids per manufacturer-specified unit if the product is an adult-use activated concentrate, edible infused product, transmucosal infused product, or transdermal infused product; or*
- ▶ *The milligram content of Active THC and all other marketed cannabinoids per container if the product is an adult-use topical infused product, a medical infused product, or a medical activated concentrate.*

Potency labeling is critical for cannabis consumer safety, just as active ingredient content is for prescriptions and proof is for alcoholic beverages. State medical and adult-use cannabis regulations generally require potency labeling but specific requirements vary substantially. Some states require potency of Δ^9 -tetrahydrocannabinol (“THC”) only while others require a full cannabinoid and terpene profile. Some states vary potency labeling requirements by product type and others do not.

Our goals in formulating a recommended standard for potency labeling are: the elimination of impertinent information while presenting meaningful information effectively, aligning with federal requirements for other products when possible, and providing a model appropriate for uniform adoption across states.

RECOMMENDATION #9 (Continued)

Effective THC vs. Active THC

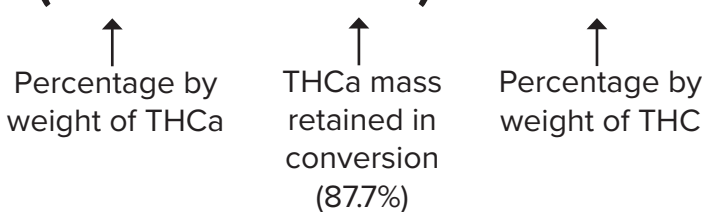
Of the more than 100 cannabinoids scientists have isolated in cannabis, researchers have insight into the effects of only a handful. THC is the most well-studied largely because it is the primary psychoactive component of cannabis.²³ Because of its implications for consumer and public safety, the Committee and a majority (64.6%) of the survey population agreed that THC potency labeling should be mandatory.

THC potency must be addressed differently for activated and non-activated products. In general, cannabis flower and non-activated concentrates²⁴ contain small amounts of THC but contain larger amounts of Δ9-Tetrahydrocannabinolic acid (“THCa”). THCa is a non-psychoactive compound that is converted to psychoactive THC through

decarboxylation. When these products are smoked or vaporized, the exposure to heat causes rapid decarboxylation and converts the THCa to THC that is then absorbed through the lungs into the bloodstream to produce a psychoactive effect.

THCa loses mass during conversion to THC, so simply adding THCa and THC values yields an inaccurate estimate of total effective THC content for a non-activated product. The difference in molecular mass must be accounted for. Following the approach taken in Nevada,²⁵ we suggest that flower and non-activated concentrate labels be required to include the percentage concentration weight by weight or weight by volume of Effective THC, which should be calculated by the laboratory that conducted potency testing according to the following formula:

$$\text{THCeffective} = (\text{THCa}\% \times 0.877) + \text{THC}\%$$


Percentage by weight of THCa THCa mass retained in conversion (87.7%) Percentage by weight of THC

In contrast, most psychoactive cannabis products that are not smoked or vaporized are decarboxylated during the manufacturing process and typically contain very little THCa but more active THC when packaged for retail. These activated cannabis products may be consumed in a variety of ways, including orally, transdermally, and sublingually. These consumption methods don't result in conversion of the remaining THCa

to THC, so the THCa does not yield psychoactive effect and is therefore irrelevant for potency labeling purposes.

Effective THC content or concentration would not accurately represent the psychoactive potential of cannabis-infused products and activated concentrates and therefore should not be used in potency labeling for these products.²⁶ Instead,

²³ The totality of available evidence indicates that THC is the only cannabinoid with substantial psychoactive effects, though it is also recognized that other cannabinoids in combination with THC produce unique effects (“the entourage effect”) and can enhance or lessen the mind-altering effects of THC. The available evidence also indicates that THCa is non-psychoactive when eaten. More research is needed concerning the psychoactive potential of cannabinoids other than THC under various conditions and when consumed in different ways. If other psychoactive potential is uncovered, regulations should be adjusted as needed for the protection of public safety.

²⁴ Here, we are referring to concentrates produced by low-heat methods, like ice water extraction and CO2 extraction, that are not decarboxylated by placement in a heated oven or any other method prior to retail packaging.

²⁵ Nevada Department of Health and Human Services. Adopted Regulation for the Medical Use of Marijuana, Sec. 8, pp. 4. LCB File No. R148-15. August 29, 2016. Retrieved from:

<http://dphh.nv.gov/uploadedFiles/dphhnhvgov/content/Reg/MedMarijuana/Adopted%20Regs%20LCB%20File%20R148-15.pdf>

²⁶ We decided Effective THC was not appropriate for activated concentrates because, as a general rule of thumb, activated concentrates are decarboxylated because they are intended to be taken orally or used in cooking and therefore the THCa must be converted to THC to yield psychoactive effects. This won't be true in every case, so regulators may consider requiring Effective THC for concentrates that are intended to be smoked or vaporized and Active THC for those that are intended to be taken orally. Percentage weight by weight (or

RECOMMENDATION #9 (Continued)

we recommend that labels for topicals, edibles, transmucosals, transdermals, and activated concentrates intended to be taken orally or used in cooking include the milligram content of THC, referred to as “Active THC.”

Voluntary Potency Labeling: All Other Marketed Cannabinoids and Terpenes

We recommend requiring cannabis product labels display the potency of THC/THCa and any other cannabinoid found to be intoxicating. Though cannabidiol (CBD), cannabigerol (CBG), cannabinol (CBN), and others have therapeutic uses and can moderate the effects of THC, they are present in miniscule amounts in raw cannabis and are generally non-psychoactive. As additional research on the psychoactivity of minor cannabinoids is published, we recommend revisiting and potentially revising these potency labeling requirements. The content of a non-psychoactive cannabinoid in each product does not provide meaningful information from a safety standpoint and therefore should be disclosed at the licensee’s discretion. Terpene content is similarly not connected to public health and safety concerns and thus should be disclosed voluntarily. The topic can be revisited when new research regarding the role of terpenes and lesser known cannabinoids becomes available.

A licensee that elects to make a claim about the content of any cannabinoid other than THC (“all other marketed cannabinoids”) or any terpene should be required to provide potency information for that cannabinoid in a manner that is substantially similar to mandatory potency labeling.

Potency Per Manufacturer-Specified Unit

Adult-use edibles, transdermals, transmucosals,

and activated concentrates packaged and labeled for sale to a consumer should be required to display milligrams of Active THC per manufacturer-specified unit (“MSU”). An MSU is a quantity of the product that the manufacturer demarcates or measures as a single portion provided that the portion contains no more Active THC than the state-imposed per-unit maximum per unit (see the Appendix for a discussion). This model provides state regulatory control over the potency of single-unit cannabis-infused products and activated concentrates as well as total THC content per container.

An adult-use edible, transdermal, transmucosal, or activated concentrate that is intended for ingestion at one time and does not exceed the per-unit THC cap is a single-unit product and should be labeled with the total milligrams of Active THC in the product (i.e., the entire product = one MSU). However, if the product is not to be eaten in one sitting or it exceeds the state-imposed per-unit THC limit, it is considered a multi-unit product. A multi-unit product (i.e., adult-use multi-unit edibles, transmucosals, transdermals, and activated concentrates) packaged for retail must display milligram content of Active THC per MSU as well as the total number of units per container. The term “unit” should not be used in product labeling but should be replaced by an appropriate descriptive term selected by the manufacturer. The consumer should be able to easily identify a single-unit portion and understand the quantity of Active THC in that portion.²⁷

Medical cannabis patients should have access to higher potency products and should be exempt from any potency limitations per MSU. Medical cannabis products packaged and labeled for sale to patients should display potency per container.

(continued)

weight by volume, as appropriate) is the common potency measurement for products that are smoked or vaporized while milligram content is more common for ingestible products, so we attempted to remain consistent with these general rules.

²⁷ Unit descriptive term examples: “one cookie” in a bag of infused cookies, “1/2 cup” in a bag of infused granola, “one fluid ounce (29.57 ml)” of a 12-fluid ounce cannabis-infused beverage packaged with a one-unit measuring device, “one square” in a chocolate bar with eight single-unit squares.

RECOMMENDATION #9 (Continued)

Potency Per Container or By Weight/Volume

MSU-based potency labeling and per-unit THC limits are not applicable for the remaining product types. Topicals are non-psychoactive and should not be subject to potency caps. The labeling on a medical or adult-use topical product packaged for retail sale should include the total milligrams of Active THC per container. A descriptive term for the container may be used. If the manufacturer wishes to recommend a specific portion of the product per use, the manufacturer may include directions for use on the labeling.

Cannabis flower has nearly immediate effects when smoked or vaporized which makes dose titration easier for consumers. For these reasons and others, flower is not a high-risk product for accidental over-ingestion. The labeling on flower dispensed to a consumer should state the actual percentage of Effective THC weight by weight. Non-activated concentrates are not subject to MSU-based labeling for largely the same reasons as flower. Their labels should include the actual percentage concentration of Effective THC weight by weight or weight by volume.

Acceptable Variance

We recommend that each state establish an acceptable variance for labeled potency of plus or minus ten percent, which is the amount of variance generally allowed by the U.S. Pharmacopeia unless otherwise stated in a drug monograph. This is helpful for infused product manufacturers in particular, as they can order product packaging with target potency printed on the packaging itself instead of having to individually label products with the actual potency

value for the batch or lot, provided that the labeled potency is within +/-10% of the batch or lot potency result.

Because the potency of cannabis flower can vary substantially based on which part of the plant was sampled, we recommend that testing laboratories be required to take at least three samples from a batch/lot of cannabis flower and to report potency results for the batch/lot as an average of the samples' potency values. The labeled potency value would then have to be within +/-10% of the average potency of the test samples taken from that batch/lot.

In addition to the potency values required as part of the Cannabis Facts panel, a manufacturer may choose to include a target potency value on the front or another visible area of the retail product packaging to increase visibility to consumers.

Format

In terms of format, we believe that cannabis potency information can be presented effectively in a manner similar to an active ingredients or "Drug Facts" panel.²⁸ In the Model Regulations, we provide numerous visual examples of a proposed standard format for cannabis potency information, which we refer to as "Cannabis Facts." The format and content requirements are modeled after those for Drug Facts on over-the-counter drug retail packages,²⁹ with some cannabis-specific modifications. Rather than specify the appearance of the Cannabis Facts panel, it is preferred to address the content in regulation and simply provide a minimum of one visual sample per product category.

²⁸ 21 C.F.R. §201.66(c)(2)

²⁹ 21 C.F.R. Part 201, Appendix A - "Examples of Graphic Enhancements Used by FDA." Accessed January 30, 2017 from: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?an=21:4.0.1.1.2.71.25.1>

RECOMMENDATION #10

CONTAINMENT TESTING STATEMENT

Containment testing statements should not be required on cannabis labels.

Members of the committee and survey respondents showed strong support for mandatory contaminant testing, which involves assessment of pesticide residues, harmful chemicals, residual solvents, microbials, mold, filth, toxins, and other substances that are unsafe for human consumption. The Committee further agreed that certain states' specifically required contaminant statements can create confusion for consumers unfamiliar with the specific regulatory requirements and complications for business operations by reducing label consistency.

For example, the Illinois Department of Agriculture requires that all medical cannabis products be labeled with "a pass/fail rating based on the laboratory's microbiological, mycotoxins, and pesticide and solvent residue analyses."³⁰ Seeing a list of contaminants on a product label, including one containing the word "toxin," surely

has negative implications for consumers and may even cause alarm. In addition, the pass/fail ratings for each contaminant test do not convey useful safety information because the product cannot be dispensed unless it passes the state's testing standards. We are not aware of any other consumer product that must contain statements about contaminant testing on the product itself, much less a list of contaminants that are not present. Consumers trust government agencies to ensure that all other products undergo appropriate testing for safety and all modern cannabis regulatory structures provide for significant consumer safety testing. As such, it seems inappropriate to require a separate and new standard for cannabis. For these reasons, we believe that contaminant testing statements should be removed from product labels altogether.

RECOMMENDATION #11

UNIVERSAL SYMBOL

Require a universal symbol that indicates the presence of THC in a cannabis product on the packaging or labeling of all finished cannabis products with a labeled potency value of at least 0.3% Effective THC or 1 milligram of Active THC per container or, if applicable, per manufacturer-specified unit.

In recent years, legal cannabis states like Colorado, Oregon, and Washington have begun requiring a "universal symbol" on cannabis packages and sometimes the actual products as well. A universal symbol is a visual warning to consumers that the product contains cannabis or THC. The Committee supports efforts to make cannabis products easily identifiable and is in favor of regulations requiring cannabis products packaged and labeled for sale to a consumer to clearly display a universal symbol, provided that the labeled potency of the product is least 0.3% Effective THC weight by weight or weight by volume or 1 milligram of Active THC per container or per MSU, as appropriate. We have excluded

products with THC content below the specified thresholds because such a small quantity of THC will have little to no noticeable effect on the average consumer, so the universal symbol is unnecessary. With respect to stamping edible products themselves with a universal symbol, as is required now in Colorado, Committee members appreciated the underlying intent, but concluded that having this requirement in addition to placement on the product package was unlikely to result in public safety benefits that justify the additional manufacturing and regulatory enforcement cost.

The Committee expressed concern that there is

³⁰ 8 Ill. Admin. Code 1000.420(d)(7)

RECOMMENDATION #11 (Continued)

no true universal symbol for cannabis products at present because each state that requires a universal symbol has come up with a distinctive design. This may limit the intuitiveness, and therefore effectiveness, of the universal symbol. With these issues in mind, we elected to independently develop a universal symbol in hopes that divorcing the design from a particular state will encourage universal adoption.

We surveyed individuals involved in cannabis business to gauge support for an industry-wide universal symbol and collect suggestions for a more intuitive design. More than three-quarters (78%) of survey respondents (n=130) supported an industry-wide universal symbol and most participants (68%) felt there should be a single universal symbol for both medical and adult-use products, as opposed to a distinct universal symbol for each.

Fifty-four participants provided qualitative

feedback regarding universal symbol design. The most common symbol was a cannabis leaf, which was mentioned in 23 out of 54 responses (42.6%). In addition, 31.5% of responses (17 total) included proposed letters or text; the most common were “THC” and “Contains Cannabis.”

Taken together, the findings suggest that most individuals working in the cannabis space would consider a cannabis leaf and “THC” enclosed in a triangle to be a reasonable and intuitive universal symbol. We have provided a model industry-wide universal symbol below, as well as a few universal symbols currently in use for comparison. In sum, we recommend that each legal cannabis state require the industry-wide universal symbol provided below on the retail packaging or labeling of every cannabis product that contains at least 0.3% Effective THC weight by weight or weight by volume or that contains at least 1 milligram of Active THC per container or, if applicable, per manufacturer-specified unit.

Recommended Industry-Wide Universal Symbol (Large and Small Format)



Some current examples of state “universal” symbols:



RECOMMENDATION #12

WARNING STATEMENTS

Require the following warning statements on labels for the specified product types:

For all cannabis products:

*“KEEP OUT OF REACH OF CHILDREN AND PETS,” and
“This product may be unlawful outside of the State of [insert state].”*

For all adult-use cannabis products:

“For use only by adults twenty-one years of age or older.”

For all medical cannabis products:

“For medical use only.”

For psychoactive cannabis products:

“This product may have intoxicating effects. Do not drive or operate heavy machinery while under the influence of cannabis.”

For all ingestible infused products and activated concentrates intended to be used in cooking, eaten, or otherwise swallowed and digested:

“Activation times vary but may be up to two (2) hours after this product is eaten or swallowed” or an alternative statement supported by data from an activation time study and approved by the Department.

Warning statements are required for many common consumer products, like alcohol and prescription drugs, and many states have similarly adopted mandatory warning statements for cannabis products. State-mandated cannabis warnings vary substantially, so the Committee considered a broad range of subjects and wording options – and presented these options to survey respondents for feedback – before settling on the warnings recommended here.

“KEEP OUT OF REACH OF CHILDREN AND PETS” and “This product may be unlawful outside of the State of [insert state]” are recommended warning statements for all cannabis products. Many states require “Keep out of reach of children,” but the Committee included pets in response to stories of pets consuming cannabis and becoming ill. “This product may be unlawful outside of the State of [insert state]” is intended to deter consumers from unlawfully transporting cannabis products across state lines, which is particularly important in states allowing adult use because tourists may not realize that taking cannabis products home is unlawful. Furthermore, it demonstrates that a state is taking steps to prevent state-legal cannabis from crossing its boundaries.

“For use only by adults twenty-one years of age or older” is recommended for all cannabis products intended for adult use. This simple but informative warning is already being used in adult-use cannabis states like Washington. “For medical use only” is a recommended warning for all medical cannabis product labels. Colorado, Nevada, Illinois, and many other medical cannabis states require something similar, but often add “by a qualifying patient” or some other patient reference. We have eliminated that extra language because terms for medical cannabis patient vary from state-to-state and our intention is to offer warnings that can be used nationwide.

We recommend that all psychoactive cannabis products contain the following warning: “This product may have intoxicating effects. Do not drive or operate heavy machinery while under the influence of cannabis.” Some states currently require all cannabis products or types of cannabis products to carry a warning about their intoxicating potential. Unfortunately, these warnings often end up on non-psychoactive products, like topicals, where they mislead consumers. As such, we encourage states to

RECOMMENDATION #12 (Continued)

distinguish between psychoactive and non-psychoactive products as we have in our model definitions and mandate the recommended warning for psychoactive products only. The portion of the warning concerning driving and operating machinery is modeled after mandatory label language for alcohol and certain medications.

“Activation times vary but may be up to two (2) hours after this product is eaten or swallowed” is a recommended warning for all ingestible cannabis-infused products and activated concentrates that are intended to be eaten or swallowed. The warning is intended to help reduce accidental overconsumption due to a lack of consumer awareness of the delayed onset of cannabis products taken orally. Consumer education is essential to truly address this issue and the recommended warning can be an effective measure in educating consumers about the risks associated with consuming additional doses before the first dose becomes effective. Though this language is intended to be sufficiently broad to cover all ingestible product types, there will likely be a marked difference in activation time when comparing transmucosal and edible products because transmucosal products do not have to be digested before entering the bloodstream. Because we lack sufficient evidence to propose an alternative statement

for transmucosal products, we suggest that manufacturers be allowed to request Department approval to use an alternative statement that is supported by data collected in a product-specific activation time study. The Department could establish standards for such studies to ensure consistency in alternative statement evaluation.

States may consider including a warning concerning health risks for women who are pregnant, breastfeeding, or planning on becoming pregnant. At present, there is insufficient information as to the effects of cannabis use on pregnant women, fertility, or breast milk, but this is clearly an area of significant concern for public health. States should monitor relevant studies and add an appropriate warning if it becomes apparent that the body of available evidence suggests significant potential for harm to babies.

It may also be important to include “Do Not Eat” on the labels of all products not intended to be taken orally in order to clearly distinguish products subject to certain food-related Health Department regulations from those that are not. Including this warning on products not intended for oral consumption is a recommended best practice but can be included in regulation as well if needed to prevent the unnecessary application of local and state food safety regulations to inedible products.

RECOMMENDATION #13

PROHIBIT UNTRUTHFUL OR MISLEADING STATEMENTS

Prohibit untruthful or misleading statements in cannabis product labeling, including health claims. Require licensees to maintain substantiation that each label statement, whether mandatory or voluntary, is truthful and not misleading.

Federal law prohibits the use of false or misleading statements in labeling for drugs, cosmetics, tobacco products, foods, supplements, and alcoholic beverages.³¹ Claims concerning a product’s impact on health or disease are limited by FDA regulation and may be considered false or misleading depending on the product type and claim content. When a product is not marketed

as a drug, its labeling may not include any claims to diagnose, mitigate, treat, cure, or prevent any disease because, by law, “disease claims” may only be made about drugs.³² Alcoholic beverage labels similarly may not include disease claims and are also subject to regulatory scrutiny for labeling that contains non-mandatory health-related statements implying curative or

³¹ Federal Food, Drug, and Cosmetic Act, Federal Alcohol Administration Act

³² See 27 C.F.R. § 101.93(g)(2) for more information on disease claims that may only be made for products marketed and sold as a drug.

therapeutic effects or a relationship between consumption and health benefits or effects.³³

States like Colorado and Minnesota have prohibited false or misleading statements in cannabis labeling, but it is less common to find specific prohibitions against health or disease claims in state cannabis regulation. In the interest of protecting consumers and aligning with federal policy, we recommend that all states with cannabis programs adopt a prohibition on false or misleading statements, including health or disease claims.

Though most reasonable businesspeople would recognize that deceptive statements are unacceptable without a rule in place, we believe it is advantageous to explicitly prohibit false and misleading statements, including health or disease claims, for several reasons. First, a specific prohibition justifies enforcement action against cannabis licensees making false or misleading claims by their primary regulators, which would be more efficient than having enforcement handled by the state entity that prosecutes false advertising claims. Second, by specifying that health or disease claims about cannabis products are false or misleading and therefore prohibited, medical cannabis licensees in compliance with the state will be protected from FDA enforcement action, which has occurred for CBD products labeled with unlawful health or disease claims. We believe many medical cannabis licensees may not be aware of federal limits on health or disease claims and an FDA enforcement action could be circumvented by prohibiting these types of claims. Finally, our

suggested prohibition protects consumers from being misled and misinformed about cannabis products, which is especially important given the current dearth of well-designed research and scientific evidence concerning the medicinal properties and health impacts of cannabis. It is highly unlikely that any state regulatory body has the resources to review scientific evidence and substantiate every health or disease claim in accordance with FDA substantiation standards,³⁴ so prohibiting such claims is a simple, temporary solution that should be revisited following federal cannabis reform.

The language provided in the Model Regulations has been adapted from language in federal labeling rules for distilled spirits and dietary supplements.³⁵

Voluntary Claim Substantiation Generally

Some common labeling items have been excluded from our recommendations because we believe they are unnecessary for the protection of health and safety but are likely to be voluntarily employed for marketing purposes. For example, producers may elect to provide information about cultivation inputs, solvents or chemicals used in manufacturing, or terpene content to appeal to certain cannabis consumers. The importance of truthful and unambiguous labeling holds whether the information provided is mandatory or voluntary, so we recommend requiring licensees to retain documentation substantiating voluntary labeling statements, just like THC potency values are substantiated by laboratory testing records.

RECOMMENDATION #14

SMALL PACKAGING LABELING COMPLIANCE

As the legal cannabis market matures the range of product and packaging options will expand, so it is important that cannabis laws and regulations offer some degree of flexibility so as not to stifle

innovation. At present, there is a great need for flexibility in terms of mandatory labeling content because products in small containers often will not have sufficient surface area to display the

³³ 27 C.F.R. § 5.42(b)(8)

³⁴ U.S. Food & Drug Agency, 2008. Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act. Retrieved from: <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm> on 11/8/2016.

³⁵ 27 C.F.R. § 5.42(a)(1) and (b)(8)

RECOMMENDATION #14 (Continued)

required information. Though some states allow required labeling information to be provided to consumers on a separate sheet at the point of sale, on the interior of a peel-back label, or in an attached accordion label, a consumer is much less likely to read information presented in these formats. Any type of labeling that is easily detached from the product packaging is likely to be lost or discarded.

In order to accommodate small packages but preserve labeling effectiveness, we recommend establishing a reduced set of labeling requirements for cannabis products in retail

packaging that does not have sufficient space for all of the mandatory label content. Cannabis products sold at retail in small packages should be required to include at least a statement of identity, net quantity of contents, the cultivator's or manufacturer's license number (as appropriate), the lot or batch code, the Cannabis Facts Panel with all required potency information, all required warnings, and the universal symbol, if applicable.³⁶ Licensees should have the option of requesting Department review of the small container labeling to ensure compliance or authorization to use a font that is smaller than would be allowed otherwise.

³⁶ The reduced labeling requirements recommended here were inspired by regulations adopted in Oregon. See OAR 333-007-0090(4).

CANNABIS PACKAGING REGULATORY RECOMMENDATIONS

RECOMMENDATION #15

CHILD-RESISTANT PACKAGING

Require all cannabis products for sale to a consumer to be packaged in a container that is child-resistant or otherwise placed within a child-resistant exit bag before the product leaves the licensed premises. In the future, this requirement should be reconsidered and eliminated for certain product types as appropriate.

Multi-unit ingestible product packages, multi-unit transdermal product packages, and activated concentrate product packages must be re-sealable and maintain child-resistant effectiveness for multiple closures.

Cannabis products in non-compliant packages may be dispensed to the elderly and persons with physical disability who experience difficulty in opening child-resistant packaging.

Child-resistant packaging is special safety packaging mandated by the Poison Prevention Packaging Act of 1970 to protect children from harm resulting from ingestion or contact with certain household products. Products required to be in child-resistant packaging range from liquid nicotine and ibuprofen to cosmetics with a certain amount of ethylene glycol.³⁷ Child-resistant packaging is a common feature of state cannabis laws and regulations but states vary in their requirements for child-resistant packaging and the application to various cannabis product types.

Policymakers, members of industry, and public health experts generally agree that ingestible cannabis-infused products in food and drink forms should be dispensed in child-resistant packaging because of their potential to appeal to children and cause significant intoxication when consumed. Committee members showed overwhelming support for mandating child-resistant packaging for all ingestible infused products and 84% of surveyed respondents concurred. Whether child-resistant packaging should be required for the remaining products is debatable because the remaining products are

less appealing to eat than infused foods and many will not produce a psychoactive effect when eaten or touched. Regardless, we found that a majority of survey respondents supported mandatory child-resistant packaging for cannabis flower (58%), concentrates (75%), and non-ingestible infused products (57%).

Though the Committee disagreed on whether child-resistant packaging is necessary for non-activated products, members ultimately supported mandatory child-resistant packaging for all cannabis products, at least until the legal cannabis industry is better established.³⁸ In light of the considerable scrutiny the industry faces at this nascent stage, it is essential that industry participants advocate for rigorous safety standards, especially for the protection of children. At present, it is likely that few parents and policymakers are aware that cannabis flower and non-activated concentrates don't cause intoxication when eaten, so it is best to adopt more restrictive rules aimed at preventing accidental ingestion by children now and adapt regulations to the realities of the product later, when cannabis is more widely accepted and

³⁷ 16 C.F.R. § 1700.14

³⁸ Though the majority of Committee members and survey respondents supported mandatory child-resistant packaging for all or nearly all products, a few participants were adamantly against mandatory child-resistant product packaging and instead thought child-resistant packaging should be required in the form of an exit bag or not at all. Reasons provided for their positions include: it doesn't protect children over 5 and older children or teens may be the primary group experiencing accidental ingestion; resealable packaging that retains child-resistant effectiveness is expensive/drives up market costs/makes black market competition more difficult; negatively impacts or blocks small companies entering the market; limits product differentiation; not eco-friendly; gives parents a false sense of security—a certain failure rate is allowed when child-resistant packaging undergoes testing, so the packaging alone is not a 100% guarantee that children aged five and under will be prevented from opening the package.

RECOMMENDATION #15 (Continued)

understood. It is important to note that mandatory child-resistant packaging alone is not a silver bullet. Public education campaigns concerning safe storage of cannabis products and mandatory child-resistant packaging are complementary measures and should be implemented concurrently.

Federal special packaging standards and test methods have been in place for decades and can easily be applied to cannabis products. We recommend defining child-resistant packaging to conform with the federal test protocol for “special packaging” established in 16 C.F.R. 1700.20, as amended in 1995 (the current version at time of writing). The Committee’s recommended definition of child-resistant packaging, which is

modeled after language used in Colorado and Oregon, is provided in the model definitions.

Following the special packaging specifications set forth in 16 C.F.R. 1700.15, we further recommend requiring that every multi-unit ingestible or transdermal cannabis-infused product be dispensed in packaging that is re-sealable and maintains its child-resistant effectiveness for at least the number of MSUs within. Licensees should also be permitted to provide a limited number of non-compliant packages for elderly or handicapped persons with difficulty opening child-resistant packaging as long as there is a conspicuous warning stating: “This package is for households without young children.”³⁹

RECOMMENDATION #16

LIQUID UNIT MEASUREMENT

Require multi-unit liquid ingestible infused products intended for adult use to be dispensed to a consumer in packaging with a device or mechanism for measuring a single-unit portion of the product.

When adult cannabis consumers in Colorado and Washington purchase a liquid ingestible product, the package is required to contain a mechanism or device for measuring a single unit of the product. This packaging requirement is recommended for the same reasons as the mandatory demarcation of each unit in multi-unit solid edibles. Single-unit (referred to in some states as “single serving”) demarcation and measurement devices became required for multi-unit products as a response to early cases of accidental over-ingestion partially resulting from a lack of clarity concerning proper dosage for edibles. Our survey findings show that cannabis industry and ancillary businesses overwhelmingly support mandatory inclusion of a measurement device or mechanism (69% in favor) with the packaging in which an adult-use multi-unit liquid ingestible product is dispensed.

The Committee shares regulators’ concerns about accidental over-ingestion and fully supports reasonable prevention measures. Thus, we recommend that every state adopt regulations mandating the use of retail packaging for liquid adult-use ingestible products with a device or mechanism for measuring a single unit.⁴⁰ Language should be sufficiently broad to allow familiar devices, like measuring cups and droppers, as well as innovative solutions. Though lawmakers and regulators in Colorado and Washington prohibit demarcation on the container itself, such as hash marks, we think demarcation should be allowed because the potential for precision loss is minor and the actual risk posed by minor loss of precision is negligible as long as potency is appropriately capped per MSU for the applicable product types (see Appendix).

³⁹ 15 U.S.C. § 1473(a)

⁴⁰ We considered recommending that a single-unit measurement device or mechanism be included with retail packaging for adult-use multi-unit transdermal infused products as well, but elected against doing so at this time due to a lack of known issues with accidental over-ingestion of transdermal products in the adult-use marketplace. It would be wise to monitor the issue and if problems do arise, a mandatory measurement device should be considered and possibly adopted.

RECOMMENDATION #17

OPAQUE PACKAGING

Require that all cannabis products be dispensed to the final consumer in opaque packaging.

Opaque cannabis packaging is currently required in most legal cannabis states and is recommended here for Ingestible Cannabis-Infused Products for two primary reasons. First, public health researchers have found evidence that opaque packaging makes products less appealing to adolescents and could help limit ingestion of the package's contents by children under the age of 7.⁴¹ Second, at the federal level, the U.S. Pharmacopeia (U.S.P.) requires light-resistant containers to protect certain drugs from the effects of light, which includes opaque containers and translucent containers affixed with an opaque covering.

As such, opaque packaging is recommended for all Ingestible Cannabis-Infused Products sold at retail in the interest of limiting underage ingestion, preserving product quality, and aligning cannabis policy with relevant federal policy. In line with the U.S.P., opaque packaging should be defined or otherwise specified to include packaging that is opaque by composition as well as packaging that may be translucent but is affixed with an opaque covering. Ideally, states should require product packaging to be opaque as well as child-resistant, but states may choose to allow placement of products in a child-resistant, opaque exit bag at the point of sale as an alternative compliance measure.

RECOMMENDATION #18

PROHIBIT PACKAGING THAT IS ATTRACTIVE TO MINORS

Prohibit cannabis product packaging that primarily appeals to minors, including packaging that depicts a minor or portrays objects, images, or cartoon figures that primarily appeal to minors. "Minor" means under the age of eighteen (18). Packaging is considered to "primarily appeal" to minors if it has special attractiveness to minors beyond the general attractiveness it has for persons of legal purchase age.

Just like state regulators, parents, and the public, the Committee wants to prevent cannabis consumption by minors. We believe that the overwhelming majority of cannabis businesses share this goal and that comprehensive regulation is the best way to keep cannabis away from young people. The Committee supports all reasonable regulatory measures aimed at reducing cannabis consumption by minors. As such, we recommend that all legal cannabis states prohibit cannabis product packaging that primarily appeals to minors, including packaging that depicts a minor or portrays objects, images, or cartoon figures that primarily appeal to minors.

Many states have already adopted similar prohibitions into regulation, but many do not specify the criteria for determining if a given package is appealing to minors or not. This lack of clarity can become problematic for both regulators and licensees. To resolve this issue, the authors of this paper researched standards for other industries to identify what types of products and packaging appeal to minors. There is a strong body of research indicating that cartoon characters, even when unfamiliar, have been found to influence children's food preferences, choices, and intake, so we agree that cartoons should not be used in cannabis product

⁴¹ Duke, J. K., Collins, K., Kimbrough-Melton, R., Baskfield, H., & Tung, G. J. Preventing unintentional ingestion of marijuana by children: A health impact assessment of packaging regulations in retail marijuana establishments in Colorado. August 2013. Retrieved from: <http://www.ucdenver.edu/academics/colleges/PublicHealth/research/ResearchProjects/piper/projects/Documents/HIA%20Final%20Report%208.20.2013.pdf> on December 23, 2016.

RECOMMENDATION #18 (Continued)

packaging.^{42, 43} We also found that the voluntary Code of Responsible Practices of the Distilled Spirits Council of the United States (DISCUS) and

Oregon's current cannabis regulations provide excellent models, which were both drawn from in the Model Regulations.^{44,45}

RECOMMENDATION #19

PROHIBIT CANNABIS PACKAGING THAT RESEMBLES PACKAGING OF CERTAIN COMMERCIALY AVAILABLE PRODUCTS

Prohibit cannabis product packaging that bears a reasonable resemblance to the trademarked or characteristic packaging of any commercially available candy, snack, baked good, or beverage.

Many medical and adult-use cannabis states prohibit cannabis product packaging that bears a reasonable resemblance to the packaging of commercially available candies, snacks, baked goods, and beverages. The purpose of this prohibition is to prevent the accidental ingestion of cannabis products mistaken for commercially available food or drinks and to limit appeal to children. We do not believe this prohibition places any unreasonable restrictions on licensees as

cannabis businesses, like other businesses, must develop a distinctive brand.

In the interest of preventing accidental ingestion of cannabis products, we recommend prohibiting cannabis product packaging that bears a reasonable resemblance to the trademarked or characteristic packaging of any commercially available candy, snack, baked good, or beverage.⁴⁶

RECOMMENDATION #20

REQUIRE PACKAGING TO PROTECT CONTENTS FROM CONTAMINATION

Require cannabis product packaging to protect the product from contamination and prohibit packaging that imparts any toxic or deleterious substance to the cannabis product.

Under the federal Food, Drug, & Cosmetic Act, a food product, dietary supplement, drug, or cosmetic is deemed adulterated if the product is contaminated or potentially contaminated, including when "its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."⁴⁷ Because cannabis product safety is currently regulated at the state level, many states that have legalized medical or

adult-use cannabis chose to adopt regulations that explicitly prohibit packaging that could transfer unsafe substances to cannabis products, rendering them adulterated if these products were subject to the FD&C Act. Such a provision sustains this basic consumer protection in the absence of federal regulatory oversight and is therefore recommended for inclusion in state cannabis packaging regulations.

⁴² Roberto, C.A., Baik, J., Harris, J. L., and Brownell, K.D. Influence of licensed characters on children's taste and snack preferences. 2010. *Pediatrics*, 126(1)

⁴³ Kraak, V.I. & Story, M. Influence of food companies' brand mascots and entertainment companies' cartoon media characters on children's diet and health: a systematic review and research needs. 2015. *Obesity Review*, 16(2).

⁴⁴ Distilled Spirits Council of the United States. Code of Responsible Practices, pg. 5. 2011. Retrieved from: https://www.distilledspirits.org/wp-content/uploads/2018/03/May_26_2011_DISCUS_Code_Word_Version1.pdf

⁴⁵ OAR 845-025-7020(3)(c) and 845-025-7000(1)

⁴⁶ Note that this prohibition is intended to prevent the replication of the look and feel of the packaging for product and brand recognition purposes rather than to limit the use of established packaging methods or container types.

⁴⁷ Food and dietary supplements: 21 USC § 342(a); Drugs: 21 USC § 351(a)(1); Cosmetics: 21 USC § 361(d)

MODEL PACKAGING AND LABELING REGULATIONS

In order to assist regulators and policy-makers, we have crafted model packaging and label regulations that incorporate the recommendations contained in this document. Use of these model regulations could help foster greater consistency across states in the U.S. That consistency, in turn, could influence eventual packaging and labeling regulations at the federal level.

DEFINITIONS

The following definitions of terms shall apply, unless the context requires otherwise:

Active THC has the same meaning as THC.

Activated Concentrate means Cannabis Concentrate that a Licensee intentionally subjected to conditions or processes that cause Decarboxylation for the purpose of converting THCa to Active THC.

Activation Time is the amount of time it will take for an average consumer to begin to feel the effects of consuming or using a Cannabis Product.

Adult means a person twenty-one years of age or older who lawfully purchases Cannabis or Cannabis Products from a Licensee for personal use by persons twenty-one years of age or older, but not for resale. The term “Adult” does not include a medical Cannabis patient.

Adult-Use Product means a Cannabis Product that is intended for consumption or use by an Adult and may be purchased by an Adult from a licensed dispensary.

Batch means:

- i. A specific quantity of Cannabis that is uniform in strain, cultivated utilizing the same growing practices, harvested within a 48-hour period at the same location, and cured under uniform conditions;
- ii. A specific quantity of Cannabis Concentrate that is produced at the same time using the same extraction methods, standard operating procedures, and Cannabis from the same Lot(s); or
- iii. A specific quantity of Cannabis-Infused Product produced at the same time using

the same Ingredients, standard operating procedures, and Cannabis from the same Lot(s) or Cannabis Concentrate from the same Lot(s).

Cannabis means all parts of the plant of the genus Cannabis, whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including Cannabis Concentrate, that is cultivated, manufactured, or dispensed by a Licensee. “Cannabis” does not include industrial hemp, nor does it include fiber produced from the stalks, oil or cake made from the seeds of the plant, the sterilized seed of the plant which is incapable of germination, or the weight of any other Ingredient combined with Cannabis to prepare Cannabis Concentrate or Cannabis-Infused Products.

Cannabis Concentrate, or “Concentrate,” means a substance obtained by separating naturally occurring chemical constituents of Cannabis, such as cannabinoids, from insoluble Cannabis plant material by mechanical, chemical, or other processes that may:

- i. Contain solvents in allowable amounts and Ingredients used to promote a desired physical state, texture, or flavor in the Cannabis Concentrate, but no other Ingredients; and
- ii. Be intended for use in the production of Cannabis-Infused Products; or
- iii. Be a finished product intended for human consumption or use.

Cannabis Product means a finished product intended for human consumption or use that is comprised partially or completely of Cannabis.

DEFINITIONS (Continued)

This term “Cannabis Product” is generally used to refer to one or more of the following: Cannabis Flower, Cannabis Concentrates, and Cannabis-Infused Products, including Ingestible and Non-Ingestible Cannabis Infused Products and all sub-categories thereof.

Cannabis product category means a defined group of Cannabis Products that are in the same form. Cannabis Product Categories are as follows:

- i. Cannabis Flower;
- ii. Cannabis Concentrates, including the following sub-categories:
 - a. Activated Concentrates; and
 - b. Non-Activated Concentrates;
- iii. Cannabis-Infused Products, including the following sub-categories:
 - a. Ingestible Cannabis-Infused Products, including the following sub-categories:
 - i. Edible Cannabis-Infused Products; and
 - ii. Transmucosal Cannabis-Infused Products;
 - b. Non-Ingestible Cannabis-Infused Products, including the following sub-categories:
 - i. Topical Cannabis-Infused Products; and
 - ii. Transdermal Cannabis-Infused Products.

Cannabis Flower, or “Flower,” means the inflorescence(s) of the mature pistillate (female) Cannabis plant.

Cannabis-Infused Product means any Cannabis Product that is comprised of Cannabis and at least one other Ingredient and is intended for use or consumption other than by smoking or vaporizing. A Cannabis-Infused Product may be an Ingestible Cannabis-Infused Product or a Non-Ingestible Cannabis-Infused Product.

Child-Resistant means designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as certified by a

qualified, third-party testing body using the test protocol described in 16 C.F.R. 1700.20 (1995). This incorporation by reference does not include any later amendments or editions to the Code of Federal Regulations.

Decarboxylation means a chemical reaction that converts an acid to a phenol and releases carbon-dioxide (CO₂); a carbon atom is removed from a carbon chain.

Department means [INSERT NAME OF STATE CANNABIS REGULATORY AGENCY].

Effective THC means the sum of the percentage by weight of THCa multiplied by 0.877 plus the percentage by weight of THC.

Exit Bag means a Child-Resistant, Opaque, sealed container provided at the point of sale in which any Cannabis Products already in Packaging that is not Child-Resistant are placed prior to leaving a licensed dispensary.

Immediate Container means the Package in direct contact with a Cannabis Product at the point of sale to a consumer.

Ingestible Cannabis-Infused Product, or “Ingestible,” means a product that contains Cannabis and at least one other Ingredient, is intended for consumption or use other than by smoking or vaporizing, is intended to be taken into the body, and is one of the following sub-categories:

- i. An Edible Cannabis-Infused Product, or “Edible,” which is an Ingestible Cannabis-Infused Product that is intended to be taken by mouth, swallowed, and primarily absorbed through the gastrointestinal tract. Edible cannabis-infused products may be Psychoactive when used as intended. Without limitation, Edible Cannabis-Infused Products may be in the form of a food, beverage, capsule, or tablet; or
- ii. A Transmucosal Cannabis-Infused Product, or “Transmucosal,” which is an Ingestible Cannabis-Infused Product that is intended

DEFINITIONS (Continued)

to be placed in a body cavity and absorbed through the mucosal lining of the cavity, and may be Psychoactive when used as intended. Transmucosal Cannabis-Infused Products include, but are not limited to, cannabis-infused tinctures, anal suppositories, lozenges, and nasal sprays.⁴⁸

Inгредиент means any substance that is used in the manufacture of a Cannabis Concentrate or Cannabis-Infused Product and that is intended to be present in the finished product.⁴⁹

Label or “Labeling” means the written, printed, or graphic matter displayed on the Packaging in which a Cannabis Product is dispensed or displayed to a consumer.⁵⁰

Licensee means any Person licensed, registered, or otherwise authorized by the Department to engage in commercial Cannabis cultivation, processing, extraction, manufacturing, packaging, labeling, testing, transportation, distribution, wholesale, delivery, or retail sale, or any allowable combination of these activities.

Lot means a Batch, or a specific identified portion of a Batch, having uniform character and quality within specified limits.

Major Food Allergen or “Allergen” means milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans and any ingredient containing a protein derived from these foods.

Manufacturer-Specified Unit, “MSU,” or “Unit” means a quantity of an Edible Cannabis-Infused Product, Transmucosal Cannabis-Infused Product, Transdermal Cannabis-Infused Product, or

Activated Concentrate that contains no more than [X milligrams]⁵¹ of Active THC and is intended to be consumed or used by an Adult on one occasion.

Medical-Use Product means a Cannabis Product that is intended for consumption or use by a qualified, registered medical Cannabis patient and may be purchased by a qualified, registered patient or a patient’s caregiver from a licensed dispensary.

Multi-Unit Product means an Edible Cannabis-Infused Product, Transmucosal Cannabis-Infused Product, Transdermal Cannabis-Infused Product, or Activated Concentrate that consists of more than one Manufacturer-Specified Unit and is intended to be consumed or used by an Adult on more than one occasion.

Non-Activated Concentrate means Cannabis Concentrate that no Licensee intentionally subjected to conditions or processes that cause Decarboxylation.

Non-Ingestible Cannabis-Infused Product, or “Non-Ingestible,” means a product that contains Cannabis and at least one other Ingredient, is intended for consumption or use other than by smoking or vaporizing, is intended for external use only, and is one of the following:

- i. A *Topical Cannabis-Infused Product*, or “Topical,” which is a Non-Ingestible Cannabis-Infused Product that is not Psychoactive when used as intended. Topical Cannabis-Infused Products include but are not limited to Cannabis-infused creams, salves, bath soaks, and lotions⁵²; or
- ii. A *Transdermal Cannabis-Infused Product*,

⁴⁸ Each state should consider whether it is necessary to create a new product sub-category for cannabis tinctures in order to exempt tinctures from state liquor laws.

⁴⁹ Adapted from 21 C.F.R. § 111.3

⁵⁰ Adapted from the definition of label in Section 201(k) of the Federal Food, Drug, and Cosmetic Act and the definition of labeling set forth in the U.S. Pharmacopoeia-National Formulary.

⁵¹ “[X milligrams]” is a placeholder for a state-imposed limit on per-unit Active THC content. The 2015 Committee was in favor of state-imposed limits on the per-unit potency of cannabis-infused products (topicals excepted) but could not reach consensus on the precise amount of Active THC that should be allowed per unit and therefore recommended that each state adopt a per-unit potency cap based on the best available evidence and the input of diverse local stakeholders and subject-matter experts. See the Appendix for more information about state policy regarding THC potency caps.

DEFINITIONS (Continued)

or “Transdermal,” which is a Non-Ingestible Cannabis-Infused Product that contains at least one skin-permeation-enhancing Ingredient to facilitate absorption through the skin into the bloodstream, and may be Psychoactive when used as intended. Transdermal Cannabis-Infused Products include but are not limited to Cannabis-infused adhesive patches that are applied to the skin surface.

Opaque refers to Packaging that does not allow the contents to be seen when unopened. Packaging may be Opaque by virtue of the specific properties of the material of which it is composed, including any coating applied to it, or by means of a secondary Opaque covering.

Package or “Packaging” means the Immediate Container in which a finished Cannabis Product is placed for retail sale to consumers and any outer container or wrapping used in the retail display of the Cannabis Product to consumers. “Package” does not include:

- i. Any shipping container or wrapping used solely for the transportation of any Cannabis Product in bulk or in quantity to Licensees;
- ii. Any shipping container or outer wrapping used by a Licensee to ship or deliver any Cannabis Product directly to consumers unless it is the only such container or wrapping⁵³; or
- iii. An Exit Bag.

Person means a natural person, partnership,

association, company, corporation, limited liability company, or organization, or a manager, agent, owner, director, servant, officer, or employee thereof; except that “Person” does not include any governmental organization.

Psychoactive means capable of affecting mental processes, such as cognition or affect, when used by a human in the intended manner. A Cannabis Product is considered Psychoactive if it is not a Topical Cannabis-Infused Product and the labeled potency is greater than three-tenths of one percent of Active THC or Effective THC, or is greater than one milligram of Active THC per Package or, if applicable, per Manufacturer-Specified Unit.

Single-Unit Product means an Edible Cannabis-Infused Product, Transmucosal Cannabis-Infused Product, Transdermal Cannabis-Infused Product, or Activated Concentrate that consists of a single Manufacturer-Specified Unit containing no more than [X milligrams]⁵⁴ of Active THC and that is intended to be consumed or used by an Adult on one occasion.

THC means Δ^9 -tetrahydrocannabinol, the principal Psychoactive constituent of Cannabis.

THCa means Δ^9 -tetrahydrocannabinolic acid, the non-Psychoactive precursor of THC.

⁵² At present, all available evidence indicates that topical cannabis products are entirely non-psychoactive when used as intended. The definition of “transdermal cannabis-infused product” presented here references a skin-permeation-enhancing ingredient, which the pharmacological research conducted as part of this project pointed to as the key distinguishing factor between topicals, which produce a localized effect only, and transdermals which are capable of a systemic, and therefore psychoactive, effect. The authors recognize that the difference between these product categories may be lost on the average cannabis consumer today but don’t think that should limit progress towards regulatory precision because businesses and consumers can and will adjust. That being said, there is no known research into whether topical cannabis products allow residual amounts of cannabinoids into the bloodstream. If it is found that at high potencies or under certain conditions a topical cannabis product has psychoactive potential, the definitions proposed here should be adjusted. It is also worth noting that cannabis topicals containing delta-9-tetrahydrocannabinol, or Active THC, may cause psychoactive effects if eaten. This has become a concern for regulators in some legal cannabis states, including Oregon, but not so much in others, so it seems appropriate for states to increase regulation of edible products if the need arises.

⁵³ Adapted from 16 C.F.R. § 1700.1(b)(3)

⁵⁴ “[X milligrams]” is a placeholder for a state-imposed limit on per-unit Active THC content. See the Appendix for more information about state policy regarding THC potency caps.

§1 - LABELING REQUIREMENTS: GENERAL

- A. Conspicuous and Unobstructed. All information required on the Labeling of a Cannabis Product sold to a consumer shall be unobstructed and conspicuous. A Licensee may affix multiple Labels to a Package, provided that no required information is completely obstructed.
- B. Text. All information required on the Labeling of a Cannabis Product sold to a consumer shall be:
1. Displayed in any legible font, provided that the lowercase letter “o” is at least one-sixteenth inch in height;
 2. Displayed in a color that contrasts conspicuously with its background; and
 3. Displayed in English, although a Licensee may choose to display required information in additional languages.
- C. Required Information. A Cannabis Product sold to a consumer shall be labeled with the following information:
1. The common or usual name of the Cannabis Product in bold type, which shall include the term “Cannabis”;
 2. The name of the Licensee that produced the Cannabis Product;
 3. The business phone number or email address of the Licensee that produced the Cannabis Product;
 4. The Batch or Lot code established by the manufacturer, which shall be a distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a Batch or Lot of Cannabis Product can be determined;
 5. The net quantity of contents of the Cannabis Product stated in both U.S. Customary and Metric (SI) Units. The statement of quantity shall be:
 - a. Stated in U.S. Customary Units and Metric (SI) Units, with the latter enclosed in parentheses;
 - b. If the product is a liquid:
 - i. Expressed in terms of fluid measure;
 - ii. Preceded by the phrase “Net Contents” or “Net”; or
 - c. If the product is a solid, semi-solid, or is viscous:
 - i. Expressed in terms of dry weight; and
 - ii. Preceded by the phrase “Net Weight,” the abbreviation “Nt. Wt.,” or “Net.”
 - d. In addition to dry weight or fluid measure, a Licensee may include the number of Units in the net quantity of contents statement if the product is a Multi-Unit Cannabis Product [e.g., Net Weight: 2 oz. (56.7 g) (10 cookies)].
 6. The Universal Symbol, if the labeled potency of the Cannabis Product as stated on the Cannabis Facts Panel is at least 0.3% Effective THC or at least one milligram of Active THC. The Universal Symbol:
 - a. Shall be at least .33 inches wide and .33 inches high;
 - b. May be downloaded from the Department’s website; and
 - c. Shall be in the following form:
 7. Required Warnings:
 - a. “KEEP OUT OF REACH OF CHILDREN AND PETS.”;
 - b. “This product may be unlawful outside of the State of [insert state].”;
 - c. If the Cannabis Product is Psychoactive, the following warning: “This product may have intoxicating effects. Do not drive or operate heavy machinery while under the influence of Cannabis.”
 - d. One of the following warnings, as applicable:
 - i. “For medical use only.”
 - ii. “For use only by adults twenty-one



§1 - LABELING REQUIREMENTS: GENERAL (Continued)

years of age or older.”

- D. Deceptive, False, or Misleading Statements Prohibited. Cannabis Product Labeling shall not contain any statement that is false or untrue in any particular, or, irrespective of falsity, directly or by ambiguity, omission, or inference, or by the addition of irrelevant, scientific or technical matter, tends to create a misleading impression.
1. A disease claim and a health-related statement shall be considered false or misleading until such claims and statements are subject to federal review and substantiation.
 2. A Licensee shall maintain substantiation that each label statement is truthful and not misleading, regardless of whether the statement is required or included at the Licensee’s discretion. Test results from an accredited and licensed cannabis testing laboratory are the only acceptable form of substantiation for cannabinoid and terpene content claims.
- E. Small Labels. Notwithstanding any other rule or regulation, a Cannabis Product that is in Packaging that, because of its size, does not have sufficient space for all of the information

required for compliance with these rules shall be labeled in accordance with the following:

1. At a minimum, the labeling shall include the following information:
 - a. Common or usual name of the product, which shall include the term “Cannabis”;
 - b. Net quantity of contents;
 - c. The license number of the cultivator or the manufacturer, as appropriate;
 - d. Batch or Lot code;
 - e. The Cannabis Facts Panel with all required information;
 - f. All required warnings;
 - g. The universal symbol, if applicable;
2. All required information not included on the labeling shall be provided to the consumer:
 - a. On a leaflet provided to the consumer at the point of sale; or
 - b. On a website maintained by Licensee that produced the product, provided that the web address is conspicuously displayed on the Label;
3. If approved by the Department, required information may be:
 - a. Displayed in a legible font that does not meet the minimum size requirement established in (B)(i); and
 - b. Displayed on a peel-back or accordion label.

§1.1 - LABELING REQUIREMENTS: CANNABIS FLOWER

- A. Required Information. In addition to the general labeling requirements set forth in Section 1(C), each Package of Cannabis Flower sold to a consumer shall be labeled with following information:
1. The license number of the Licensee who cultivated the Cannabis Flower;
 2. A Cannabis Facts Panel that shall:
 - a. Include the percentage concentration of Effective THC by weight;
 - b. Include the percentage concentration of each additional marketed cannabinoid and terpene by weight, if applicable;
 - c. Specify the reference weight (e.g., “Active ingredient in each gram”); and
 - d. Be in substantially the same form as the following:

Cannabis Facts
Active Ingredient in each gram

Effective THC.....23%

Visual Sample 1 – Cannabis Facts: Cannabis Flower, Mandatory Information Only

§1.1 - LABELING REQUIREMENTS: CANNABIS FLOWER (Continued)

Cannabis Facts

Active Ingredient in each gram

Effective THC.....	23%
CBDa.....	2.4%
CBG.....	0.8%
Limonene.....	0.6%
B-Myrcene.....	0.4%

Visual Sample 1.1 – Cannabis Facts: Cannabis Flower, Mandatory and Voluntary Information

§1.2 - LABELING REQUIREMENTS: CANNABIS CONCENTRATES

- A. Required Information. In addition to the general labeling requirements set forth in Section 1(C), each Package of Cannabis Concentrate sold to a consumer shall be labeled with following information:
1. The license number of the Licensee who produced the Cannabis Concentrate.
 2. If the Cannabis Concentrate is intended to be cooked with, eaten, or otherwise swallowed and digested, a Nutrition Facts Panel designed in accordance with 21 CFR § 101.9(c) and (d), hereby incorporated by reference, except that:
 - a. “Manufacturer-Specified Unit” shall replace “Serving Size” in the incorporated regulations, except as otherwise specified in this section;
 - b. The term “Serving Size” on the Nutrition Facts Panel shall be replaced with “Recommended Single Portion” or “One Portion”; and
 - c. The word “Serving” in “Amount Per Serving” on the Nutrition Facts Panel shall be replaced with a descriptive term for the Manufacturer-Specified Unit that is appropriate for the product type and enables a reasonable consumer to intuitively determine how much of the product is intended to be consumed or used on a single occasion. The descriptive term for the Manufacturer-Specified Unit used in the Nutrition Facts Panel shall be the same as the descriptive term for the Manufacturer-Specified Unit used in the Cannabis Facts Panel for a given product.
 3. An Ingredients list that shall:
 - a. Include all Ingredients in the Cannabis Concentrate listed by common or usual name in descending order of predominance by weight;
 - b. Include “Cannabis” followed by the part of the plant (e.g., flower, trim) from which the Cannabis Concentrate is derived in parentheses; and
 - c. Be located immediately below the Nutrition Facts Panel, when present.
 - d. Any residual solvent present in a Cannabis Concentrate in an amount that is less than or equal to the acceptable limit established in Department regulations and that is not intended to be part of the finished Cannabis Concentrate may be excluded from the Ingredients list.
 - e. Any substance that is present in a Cannabis Concentrate in an insignificant amount and does not have any technical or functional effect in the finished product may be excluded from the Ingredients list.
 - f. An Ingredients list may be excluded from the Labeling of any Cannabis Concentrate that contains only Ingredients derived from Cannabis.
 4. An Allergen statement that shall declare the presence of Major Food Allergens in plain language, using the name of the food source from which each Major Food

§1.2 - LABELING REQUIREMENTS: CANNABIS CONCENTRATES (Continued)

- Allergen is derived;
- a. An Allergen statement may be excluded from the Labeling of any Cannabis Concentrate that is not intended to be cooked with, eaten, or otherwise swallowed and digested.
 - b. The Allergen statement shall be presented in the following manner:
 - i. In list form, following the word “Contains.” For example, “Contains Milk, Wheat, Egg, and Walnuts”; or
 - ii. In the Ingredients list, in parentheses following the common or usual name of the ingredient that is derived from or contains the Major Food Allergen.
 - c. As used in this section, “name of the food source from which each major food allergen is derived” means the name of the food major food allergen, except that:
 - i. In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts);
 - ii. In the case of Crustacean shellfish, it means the name of the species of Crustacean shellfish (for example, crab, lobster, or shrimp); and
- iii. The names “egg” and “peanuts”, as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the term “soy”, “soybean”, or “soya” may be used instead of “soybeans”.
5. A Cannabis Facts Panel containing the following information:
- a. If the Cannabis Concentrate is a Non-Activated Concentrate, the Cannabis Facts Panel shall:
 - i. Include the percentage concentration of Effective THC by weight or by volume;
 - ii. Include the percentage concentration of each additional marketed cannabinoid and terpene by weight or by volume, if applicable;
 - iii. Specify the reference weight or volume (e.g., “Active ingredient in each gram”); and
 - iv. Be in substantially the same form as the following:

Cannabis Facts	
Active Ingredient in each gram	
Effective THC.....	15%

Visual Sample 2 – Cannabis Facts: Non-Activated Concentrates, Mandatory Information Only

Cannabis Facts	
Active Ingredient in each fluid ounce	
Effective THC.....	15%
CBG.....	0.8%
Limonene.....	0.1%

Visual Sample 2.1 – Cannabis Facts: Non-Activated Concentrate, Mandatory and Voluntary Information

§1.2 - LABELING REQUIREMENTS: CANNABIS CONCENTRATES (Continued)

- b. If the Cannabis Concentrate is a Medical-Use Activated Concentrate or an Adult-Use Single-Unit Activated Concentrate, the Cannabis Facts Panel shall:

i. Include the milligrams of Active THC per Package;

ii. Include the milligrams of each additional marketed cannabinoid and terpene per Package, if applicable;

iii. Include the term “Package” (e.g., “Active ingredient in each Package”), a substitute term that is appropriate
- for the Package type (e.g., “Active ingredient in each Bottle”), or a descriptive term for the product that is appropriate for the product type and enables a reasonable consumer to intuitively determine that the milligrams of Active THC listed on the Cannabis Facts Panel represents the total amount of Active THC in the product (e.g., Active ingredient in each Cannabis Oil Syringe”); and
- iv. Be in substantially the same form as the following:

Cannabis Facts	
Active Ingredient in each syringe	
Active THC.....	9 mg

Visual Sample 2.2 – Cannabis Facts: Single-Unit Adult-Use Activated Concentrate or Medical-Use Activated Concentrate, Mandatory Information Only

Cannabis Facts	
Active Ingredient in each tub	
Active THC.....	200 mg
CBD.....	50 mg
CBN.....	10 mg

Visual Sample 2.3 – Cannabis Facts: Single-Unit Adult-Use Activated Concentrate or Medical-Use Activated Concentrate, Mandatory and Voluntary Information

- c. If the Cannabis Concentrate is an Adult-Use Multi-Unit Activated Concentrate, the Cannabis Facts Panel shall:

i. Include the milligrams of Active THC per Manufacturer-Specified Unit;

ii. Include the milligrams of each additional marketed cannabinoid and terpene per Manufacturer-Specified Unit, if applicable;

iii. Include a statement of the number of Units and the total milligrams of Active THC in the Package;

iv. Include a descriptive term for the
- Manufacturer-Specified Unit that is appropriate for the product type and enables a reasonable consumer to intuitively determine how much of the product is intended to be consumed or used on a single occasion [e.g. “Active ingredient per dropper (10 per bottle).”]. The descriptive term for the Manufacturer-Specified Unit used in the Cannabis Facts Panel shall be the same as the descriptive term for the Manufacturer-Specified Unit

§1.2 - LABELING REQUIREMENTS: CANNABIS CONCENTRATES (Continued)

used in the Nutrition Facts Panel for a given product; and

v. Be in substantially the same form as the following:

Cannabis Facts

Active Ingredient in each dropper (10 per Bottle)

Active THC.....7.5 mg (75 mg per Bottle)

Visual Sample 2.4 – Cannabis Facts: Multi-Unit Adult-Use Activated Concentrate, Mandatory Information Only, Format Option 1

Cannabis Facts

Active Ingredient in each dropper (10 per Bottle)

Active THC.....7.5 mg (75 mg per Bottle)

CBD.....10 mg

CBN.....2 mg

Visual Sample 2.5 – Cannabis Facts: Multi-Unit Adult-Use Activated Concentrate, Mandatory and Voluntary Information, Format Option 1

Cannabis Facts

Active Ingredient in each dropper

Active THC.....9 mg

4 Droppers Per Bottle (36 mg Active THC Total)

Visual Sample 2.6 – Cannabis Facts: Multi-Unit Adult-Use Activated Concentrate, Mandatory Information Only, Format Option 2

Cannabis Facts

Active Ingredient in each dropper

Active THC.....9 mg

CBD.....10 mg

4 Droppers Per Bottle (36 mg Active THC Total)

Visual Sample 2.7 – Cannabis Facts: Multi-Unit Adult-Use Activated Concentrate, Mandatory and Voluntary Information, Format Option 2

§1.2 - LABELING REQUIREMENTS: CANNABIS CONCENTRATES (Continued)

6. In addition to the general required warnings set forth in Section 1(C), each Package of Activated Concentrate that is intended to be cooked with, eaten, or otherwise swallowed⁵⁵ and digested shall be labeled with following information:
 - a. “Activation times vary but may be up to two (2) hours when this product is eaten or swallowed.”; or
 - b. An alternative statement of activation time that is specific to a product or product category, based on findings from research conducted by a Licensee or other entity on product activation time conducted in accordance with established scientific research standards, and approved by the Department for use within specified limits.
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§1.3 - LABELING REQUIREMENTS: INGESTIBLE CANNABIS-INFUSED PRODUCTS

- A. Required Information. In addition to the general labeling requirements set forth in “§1 - Labeling Requirements: General,” each Package of Ingestible Cannabis-Infused Product sold to a consumer shall be labeled with following information:
1. The license number of the Licensee who manufactured the Ingestible Cannabis-Infused Product;
 2. If the product is an Edible Cannabis-Infused Product, a Nutrition Facts Panel designed in accordance with 21 CFR § 101.9(c) and (d), hereby incorporated by reference, except that:
 - a. “Manufacturer-Specified Unit” shall replace “Serving Size” in the incorporated regulations, except as otherwise specified in this section;
 - b. The term “Serving Size” on the Nutrition Facts Panel shall be replaced with “Recommended Single Portion” or “One Portion”; and
 - c. The word “Serving” in “Amount Per Serving” on the Nutrition Facts Panel shall be replaced with a descriptive term for the Manufacturer-Specified Unit that is appropriate for the product type and enables a reasonable consumer to intuitively determine how much of the product is intended to be consumed or used on a single occasion. The descriptive term for the Manufacturer-Specified Unit used in the Nutrition Facts Panel shall be the same as the descriptive term for the Manufacturer-Specified Unit used in the Cannabis Facts Panel for a given product.
 3. An Ingredients list that shall:
 - a. Include all Ingredients in the Ingestible Cannabis-Infused Product listed by common or usual name in descending order of predominance by weight;
 - b. Include “Cannabis” followed by the part of the plant (e.g., flower, trim) or form of concentrate (e.g., shatter, oil, infused butter) used as input material in the manufacturing process, enclosed in parentheses; and
 - c. Be located immediately below the Nutrition Facts Panel.
 - d. Any residual solvent present in an Ingestible Cannabis-Infused Product in an amount that is less than or equal to the acceptable limit established in Department regulations and that is not intended to be part of the finished Ingestible Cannabis-Infused Product may be excluded from the Ingredients list.
 - e. Any substance that is present in an Ingestible Cannabis-Infused Product in

⁵⁵ It is important to note that transmucosal products activate more quickly than other Ingestible Infused Products. However, more research is needed to determine the activation time differences between edibles and transmucosal products before more specific activation time statements can be developed.

§1.3 - LABELING REQUIREMENTS: INGESTIBLE CANNABIS-INFUSED PRODUCTS (Continued)

- an insignificant amount and does not have any technical or functional effect in the finished product may be excluded from the Ingredients list.
4. An Allergen statement that shall declare the presence of Major Food Allergens in plain language, using the name of the food source from which each Major Food Allergen is derived.
 - a. The Allergen statement shall be presented in the following manner:
 - i. In list form, following the word “Contains.” For example, “Contains Milk, Wheat, Egg, and Walnuts”; or
 - ii. In the Ingredients list, in parentheses following the common or usual name of the ingredient that is derived from or contains the Major Food Allergen.
 - b. As used in this section, “name of the food source from which each major food allergen is derived” has the same meaning as used in “§1.2 – Labeling Requirements: Cannabis Concentrates” when discussing major food allergens.
 5. A Cannabis Facts Panel containing the following information:
 - a. If the Ingestible Cannabis-Infused Product is a Medical-Use Ingestible Cannabis-Infused Product or an Adult-Use Single-Unit Ingestible Cannabis-Infused Product, the Cannabis Facts Panel shall:
 - i. Include the milligrams of Active THC per Package;
 - ii. Include the milligrams of each additional marketed cannabinoid and terpene per Package;
 - iii. Include the term “Package” (e.g., “Active ingredient in each Package”), a substitute term that is appropriate for the Package type (e.g., “Active ingredient in each Bottle”), or a descriptive term for the product that is appropriate for the product type and enables a reasonable consumer to intuitively determine that the milligrams of Active THC listed on the Cannabis Facts Panel represents the total amount of Active THC in the product (e.g., “Active ingredient in each cookie”); and
 - iv. Be in substantially the same form as the following:

Cannabis Facts
Active Ingredient in each cookie

Active THC.....7.5 mg

Visual Sample 3 – Cannabis Facts: Adult-Use Single-Unit Ingestible Cannabis-Infused Product, Mandatory Information Only

Cannabis Facts
Active Ingredient in each container

Active THC.....7.5 mg

CBD.....10 mg

CBN.....2 mg

Visual Sample 3.1 – Cannabis Facts: Adult-Use Single-Unit Ingestible Cannabis-Infused Product, Mandatory and Voluntary Information

§1.3 - LABELING REQUIREMENTS: INGESTIBLE CANNABIS-INFUSED PRODUCTS (Continued)

Cannabis Facts
Active Ingredient in each package of cookies

Active THC.....250 mg

Visual Sample 3.2 – Cannabis Facts: Medical-Use Ingestible Cannabis-Infused Product, Mandatory Information Only

Cannabis Facts
Active Ingredient in each bag of granola

Active THC.....250 mg

CBD.....100 mg

CBN.....5 mg

Visual Sample 3.3 – Cannabis Facts: Medical-Use Ingestible Cannabis-Infused Product, Mandatory and Voluntary Information

- b. If the Ingestible Cannabis-Infused Product is an Adult-Use, Multi-Unit Ingestible Cannabis-Infused Product, the Cannabis Facts Panel shall:
 - i. Include the milligrams of Active THC per Manufacturer-Specified Unit;
 - ii. Include the milligrams of each additional marketed cannabinoid and terpene per Manufacturer-Specified Unit;
 - iii. Include a statement of the number of Units and the total milligrams of Active THC in the Package;
 - iv. Include a descriptive term for the Manufacturer-Specified Unit that is appropriate for the product type and enables a reasonable consumer to intuitively determine how much

- v. Be in substantially the same form as the following:
- of the product is intended to be consumed or used on a single occasion [e.g., “Active ingredient in each lozenge (15 per container)” or “Active ingredient in each 10 ml capful” with a statement of the number of capfuls per bottle elsewhere in the Cannabis Facts Panel]. The descriptive term for the Manufacturer-Specified Unit used in the Cannabis Facts Panel shall be the same as the descriptive term for the Manufacturer-Specified Unit used in the Nutrition Facts Panel for a given product; and

Cannabis Facts
Active Ingredient in each lozenge (15 per container)

Active THC.....5 mg (75 mg per container)

Visual Sample 3.4 – Cannabis Facts: Multi-Unit Ingestible Cannabis-Infused Product, Mandatory Information Only, Format Option 1

§1.3 - LABELING REQUIREMENTS: INGESTIBLE CANNABIS-INFUSED PRODUCTS (Continued)

Cannabis Facts

Active Ingredient in each lozenge (15 per container)

Active THC.....5 mg (75 mg per container)

CBG.....0.5 mg

Visual Sample 3.5 – Cannabis Facts: Multi-Unit Ingestible Cannabis-Infused Product, Mandatory and Voluntary Information, Format Option 1

Cannabis Facts

Active Ingredient in each 10 ml capful

Active THC.....7.5 mg

Four 10 ml Capfuls Per Bottle (30 mg of Active THC Total)

Visual Sample 3.6 – Cannabis Facts: Multi-Unit Liquid Ingestible Cannabis-Infused Product, Mandatory Information Only, Format Option 2

Cannabis Facts

Active Ingredient in each 10 ml capful

Active THC.....7.5 mg

CBD.....10 mg

CBD.....2 mg

Four 10 ml Capfuls Per Bottle (30 mg of Active THC Total)

Visual Sample 3.7 – Cannabis Facts: Multi-Unit Liquid Ingestible Cannabis-Infused Product, Mandatory and Voluntary Information, Format Option 2

6. In addition to the general required warnings set forth in “§1 - Labeling Requirements: General,” each Package of Ingestible Cannabis-Infused Product sold to a consumer shall be labeled with following information:
 - a. “Activation times vary but may be up to two (2) hours when this product is eaten or swallowed.”⁵⁶; or
 - b. An alternative statement of activation time that is specific to a product or product category, based on findings from research conducted by a Licensee or other entity on product activation
7. Consumption advice, if the Ingestible Cannabis-Infused Product is an Adult-Use Product. Consumption advice shall include the phrase “CONSUMPTION ADVICE:” followed by a statement that identifies the amount of product recommended for consumption on a single occasion, which shall be less than or equivalent to the Manufacturer-Specified Unit, and time conducted in accordance with established scientific research standards, and approved by the Department for use within specified limits.

⁵⁶ See Footnote 55

§1.3 - LABELING REQUIREMENTS: INGESTIBLE CANNABIS-INFUSED PRODUCTS (Continued)

the minimum length of time that an Adult should wait before consuming another Unit.

- a. Example: “CONSUMPTION ADVICE: Until you are familiar with the effects of this product, eat only one square of the chocolate bar and wait a minimum of XX minutes before consuming another portion.”
 - b. Consumption advice may include suggestions or identify resources for consumers who have accidentally overconsumed.
 - c. Consumption advice shall be in bold text and shall be located directly above, below, or next to the Cannabis Facts Panel.
-

§1.4 - LABELING REQUIREMENTS: NON-INGESTIBLE CANNABIS-INFUSED PRODUCTS

- A. Required Information. In addition to the general labeling requirements set forth in “§1 - Labeling Requirements: General,” each Package of Non-Ingestible Cannabis-Infused Product sold to a consumer shall be labeled with following information:
1. The license number of the Licensee who manufactured the Non-Ingestible Infused Product;
 2. An Ingredients list that shall:
 - a. Include all Ingredients in the Non-Ingestible Cannabis-Infused Product listed by common or usual name in descending order of predominance by weight; and
 - b. Include “Cannabis” followed by the part of the plant (e.g., flower, trim) or form of concentrate (e.g., rosin, oil, infused butter) used as input material in the manufacturing process, enclosed in parentheses.
 - c. Any residual solvent present in a Non-Ingestible Cannabis-Infused Product in an amount that is less than or equal to the acceptable limit established in Department regulations and that is not intended to be part of the finished Non-Ingestible Cannabis-Infused Product may be excluded from the Ingredients list.
 - d. Any substance that is present in a Non-Ingestible Cannabis-Infused Product in an insignificant amount and does not have any technical or functional effect in the finished product may be excluded from the Ingredients list.
 3. A Cannabis Facts Panel containing the following information:
 - a. If the product is a Medical, Non-Ingestible Cannabis-Infused Product, a Topical Cannabis-Infused Product, or an Adult-Use Single-Unit Transdermal Cannabis-Infused Product, the Cannabis Facts Panel shall:
 - i. Include the milligrams of Active THC per Package;
 - ii. Include the milligrams of each additional marketed cannabinoid and terpene per Package, if applicable;
 - iii. Include the term “Package” (e.g., “Active ingredient in each Package”), a substitute term that is appropriate for the Package type (e.g., “Active ingredient in each Jar”), or a descriptive term for the product that is appropriate for the product type and enables a reasonable consumer to intuitively determine that the milligrams of Active THC listed on the Cannabis Facts Panel represents the total amount of Active THC in the product (e.g., “Active ingredient in each transdermal patch”); and
 - iv. Be in substantially the same form as the following:

§1.4 - LABELING REQUIREMENTS: NON-INGESTIBLE CANNABIS-INFUSED PRODUCTS (Continued)

Cannabis Facts
Active Ingredient in each package

Active THC.....125 mg

Visual Sample 4 – Cannabis Facts: Topical Cannabis-Infused Product or Medical-Use Transdermal Cannabis-Infused Product, Mandatory Information Only

Cannabis Facts
Active Ingredient in each container

Active THC.....200 mg
CBG.....200 mg

Visual Sample 4.1 – Cannabis Facts: Topical Cannabis-Infused Product or Medical-Use Transdermal Cannabis-Infused Product, Mandatory and Voluntary Information

Cannabis Facts
Active Ingredient in each transdermal patch

Active THC.....10 mg

Visual Sample 4.2 – Cannabis Facts: Adult-Use Single-Unit Transdermal Cannabis-Infused Product, Mandatory Information Only

Cannabis Facts
Active Ingredient in each transdermal patch

Active THC.....10 mg
CBDV.....5 mg
CBN.....5 mg

Visual Sample 4.3 – Cannabis Facts: Adult-Use Single-Unit Transdermal Cannabis-Infused Product, Mandatory and Voluntary Information

- b. If the product is an Adult-Use, Multi-Unit Transdermal Cannabis-Infused Product, the Cannabis Facts Panel shall:

i. Include the milligrams of Active THC per Manufacturer-Specified Unit;

ii. Include the milligrams of each additional marketed cannabinoid and terpene per Manufacturer-Specified Unit, if applicable;

iii. Include a statement of the number of Units and the total milligrams of Active THC in the Package;

§1.4 - LABELING REQUIREMENTS: NON-INGESTIBLE CANNABIS-INFUSED PRODUCTS (Continued)

- iv. Include a descriptive term for the Manufacturer-Specified Unit that is appropriate for the product type and enables a reasonable consumer to intuitively determine how much of the product is intended to be consumed or used on a single occasion [e.g., “Active ingredient in each gel stamp (10 per container)” or “Active ingredient in each transdermal patch” with a statement of the number of patches per package elsewhere in the Cannabis Facts Panel]. The descriptive term for the Manufacturer-Specified Unit used in the Cannabis Facts Panel shall be the same as the descriptive term for the Manufacturer-Specified Unit used in the Nutrition Facts Panel for a given product; and
- v. Be in substantially the same form as the following:

Visual Sample 4.4 – Cannabis Facts: Adult-Use Multi-Unit Transdermal Cannabis-Infused Product, Mandatory Information Only, Format Option 1

Cannabis Facts
Active Ingredient in each gel stamp (10 per container)
Active THC.....9 mg (90 mg Total)

Visual Sample 4.5 – Cannabis Facts: Adult-Use Multi-Unit Transdermal Cannabis-Infused Product, Mandatory and Voluntary Information, Format Option 1

Cannabis Facts
Active Ingredient in each gel stamp (10 per container)
Active THC.....9 mg (90 mg Total)
CBD.....9 mg

Visual Sample 4.6 – Cannabis Facts: Adult-Use Multi-Unit Transdermal Cannabis-Infused Product, Mandatory Information Only, Format Option 2

Cannabis Facts
Active Ingredient in each gel stamp
Active THC.....9 mg (90 mg Total)
10 Gel Stamps Per Container (90 mg of Active THC Total)

§1.4 - LABELING REQUIREMENTS: NON-INGESTIBLE CANNABIS-INFUSED PRODUCTS (Continued)

Cannabis Facts

Active Ingredient in each gel stamp

Active THC.....9 mg (90 mg Total)

CBD.....9mg

10 Gel Stamps Per Container (90 mg of Active THC Total)

Visual Sample 4.7 – Cannabis Facts: Adult-Use Multi-Unit Transdermal Cannabis-Infused Product, Mandatory and Voluntary Information, Format Option 2

§2 - PACKAGING REQUIREMENTS: GENERAL

- A. Child-Resistant Packaging or Exit Bag Required. A Cannabis Product packaged for sale to a consumer shall be in Child-Resistant Packaging or placed within a Child-Resistant Exit Bag at the point of sale, unless otherwise specified in this Section.
1. A Multi-Unit Product shall be packaged for sale to a consumer in Child-Resistant Packaging that is capable of being re-sealed and made Child-Resistant again at least as many times as the number of Units in the product.
 2. Upon request from an elderly or disabled person who experiences significant difficulty opening Child-Resistant containers, a Licensee may dispense Cannabis Products to the affected person in Packaging that is not Child-Resistant and need not place the non-compliant Packages in an Exit Bag at the point of sale. Each non-compliant Package shall be conspicuously labeled with one of the following warnings:
 - a. "This Package for Households Without Young Children."; or
 - b. "Package Not Child-Resistant."⁵⁷
- B. Opaque Packaging Required. All Ingestible Cannabis-Infused Products packaged for sale to a consumer shall be in Opaque Packaging.
- C. Packaging Shall Protect from Contamination. Cannabis Product Packaging shall protect the product from contamination and shall not impart any toxic or deleterious substance to the Cannabis Product.
- D. Packaging that Primarily Appeals to Minors Prohibited. Cannabis Product Packaging shall not primarily appeal to minors.
1. Packaging that primarily appeals to minors includes, without limitation, Packaging that:
 - a. Depicts a minor;
 - b. Portrays objects, images, celebrities, or cartoon figures that primarily appeal to minors or are commonly used to market products to minors; or
 - c. Otherwise has special attractiveness for minors beyond the general attractiveness for adults.
 2. As used in this section, "minor" means an individual under the age of eighteen (18).
 3. As used in this section, "cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:
 - a. The use of comically exaggerated features;
 - b. The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or
 - c. 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.

⁵⁷ Adapted from an exemption to the special packaging requirements established under the federal Poison Prevention Packaging Act of 1970. See 16 CFR § 1700.5.

§2 - PACKAGING REQUIREMENTS: GENERAL (Continued)

- E. Reasonable Resemblance to Trademarked Products Prohibited. Cannabis Product Packaging shall not bear any reasonable resemblance to the trademarked or characteristic Packaging of any commercially available candy, snack, baked good, or beverage.
- F. Unit Demarcation or Separation. Each Unit in a Multi-Unit Product packaged for sale to an Adult consumer shall be physically demarked in a manner that enables a reasonable Adult consumer to intuitively determine how much of the product constitutes one Unit of the product.
1. Each demarked Unit of a product shall be easily separable in order to allow an average Adult to physically separate, with minimal effort, individual Units of the product.
 2. A liquid Multi-Unit Ingestible Cannabis-Infused Product shall be sold to an Adult consumer in Packaging that contains an instrument that enables a reasonable Adult consumer to intuitively measure one Unit of the liquid product. Permissible liquid Unit measuring instruments include, without limitation:
 - a. A measuring instrument that is within the cap or closure of the Immediate Container; and
 - b. Hash marks and other forms of physical demarcation on the Package containing the liquid Ingestible Cannabis-Infused Product, provided that the demarcation is on the Immediate Container or a component of the Packaging that is not easily removable.
 3. An Activated Concentrate, Edible Cannabis-Infused Product, Transmucosal Cannabis-Infused Product, or Transdermal Cannabis-Infused Product that is intended for an Adult consumer and is of a type that is impractical to clearly demark or easily separate into Single-Unit portions shall contain no more than [X milligrams]⁵⁸ of Active THC per Package.

⁵⁸ See footnote 54

APPENDIX

DISCUSSION: STATE-IMPOSED THC POTENCY LIMITS

All commercial adult-use cannabis programs impose a cap on the maximum allowable amount of THC per serving, or single “unit” of ingestible cannabis-infused products. Alaska, Oregon, and Massachusetts establish a 5 mg of THC per unit limitation, while California, Colorado, Nevada, Maine, and Washington set a 10 mg cap per unit. Many states also impose caps on the total amount of THC that may be contained within a multi-unit cannabis-infused product or within a multi-unit package. Alaska and Oregon, taking the most conservative approach, cap multi-unit cannabis-infused edibles at 50 mg of THC; however, a cap of 100 mg of THC per multi-unit cannabis-infused product remains the industry norm in adult-use markets.

Although it has been argued that potency caps unduly limit consumer choices, state regulators have defended the implementation of these policies as a preventative measure against accidental and over-consumption of THC. These provisions are imposed primarily in response to cases of accidental over-ingestion of THC resulting from the availability of small, high-potency Cannabis Products, coupled with a lack of consumer education in edibles potency and proper administration.

In addition to legislative intervention, the cannabis industry has attempted to address these public safety issues from an educational standpoint. The phrase “Start Low & Go Slow” has been employed to educate consumers about best practices for first-time infused-product use and to encourage new users to consume cannabis safely and responsibly. Informational tools like this are often provided by dispensaries at the point-of-sale or displayed as informational videos in waiting rooms that provide links to additional online resources. Notwithstanding the different approaches taken to address these concerns, there is industry-wide agreement that responsible cannabis-infused product consumption begins with an informed consumer.

Participants in the cannabis industry and the various experts we consulted supported clear labeling of the amount of THC in a single-use unit of an adult-use ingestible infused product. Cannabis industry participants and experts also supported the imposition of a cap on the permissible amount of THC that an adult-use Cannabis Product may contain; however, there was a lack of consensus concerning the appropriate numerical limitation.

Our discussions with cannabis-infused product manufacturers and dispensaries indicated that consumers are often looking for higher potency products but that this trend appears to be changing over time. For some people, 10 mg of THC is a comfortable amount; for others, especially novice users, it can be a bit too much. Because cannabis products affect people differently, more research is needed before a model potency cap can be suggested. As the adult-use market matures we will develop a better understanding as to what is the most appropriate per unit potency of ingestible and transdermal cannabis-infused products; however, at this time, we recommend each state consider these factors while drafting regulations and to select the per-unit potency cap determined to be appropriate in accordance with stakeholder interests and the scientific evidence currently available.

Please note, that a THC potency cap should not be required for topical cannabis-infused products because they are not psychoactive, nor should it be for medical cannabis-infused products because of the varying potency needs of medical cannabis patients.