

Medical Marijuana Edible Research



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Background



- ADHS adopted AZ Medical Marijuana Act ARS Title 36 Chapter 28.1 in 2010
- ADHS adopted rules AAC Title 9, Chapter 17 in 2011
- CCPHSD adopted Edible Food Products Ordinance as part of the County Food Code in 2011
- CCPHSD Edible project proposal approved by ADHS 2014

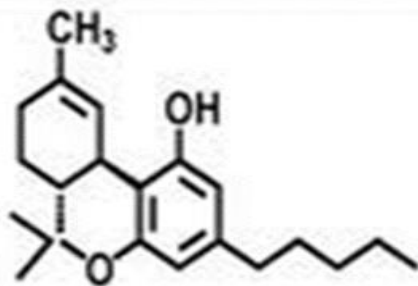
What is a Medible?

- Contains medicinal marijuana (tetrahydrocannabinol THC or cannabidiol CBD)
- PHF (TCS)?
- Extraction types?
- How are active ingredients applied?

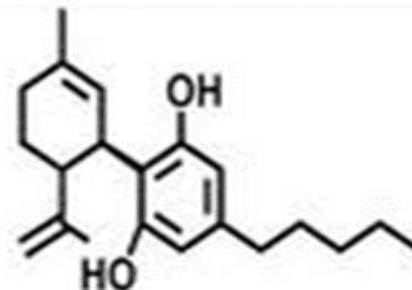


What are the Active Ingredients?

- THC – tetrahydrocannabinol this is the principal psychoactive substance in cannabis (decarboxylation to produce active form)
- CBD – cannabidiol there are over 85 different types of CBDs in cannabis. These are non-psychoactive chemicals



Δ^9 -tetrahydrocannabinol
(THC)



Cannabidiol
(CBD)

Who Regulates Medibles?

- Arizona State laws reference edibles, but do not regulate processing
- Coconino County is currently the only jurisdiction in state that regulates the processing of edibles as part of the Food Code
- Edible use is currently on rise in Arizona – dispensaries report 20% to 25% increase of total sales



Project Scope – Learn from Dispensaries, Develop Guidelines & Conduct Survey



Colorado & Washington

What we learned from their codes and mistakes:

- Extraction
- Testing
- Labeling
- Packaging
- Processing



How is an edible made?

- What, no ground up plant?



Trim



Common Extraction Methods

1. Butter
2. CO₂
3. Butane, n-butane
4. Alcohol
5. Other

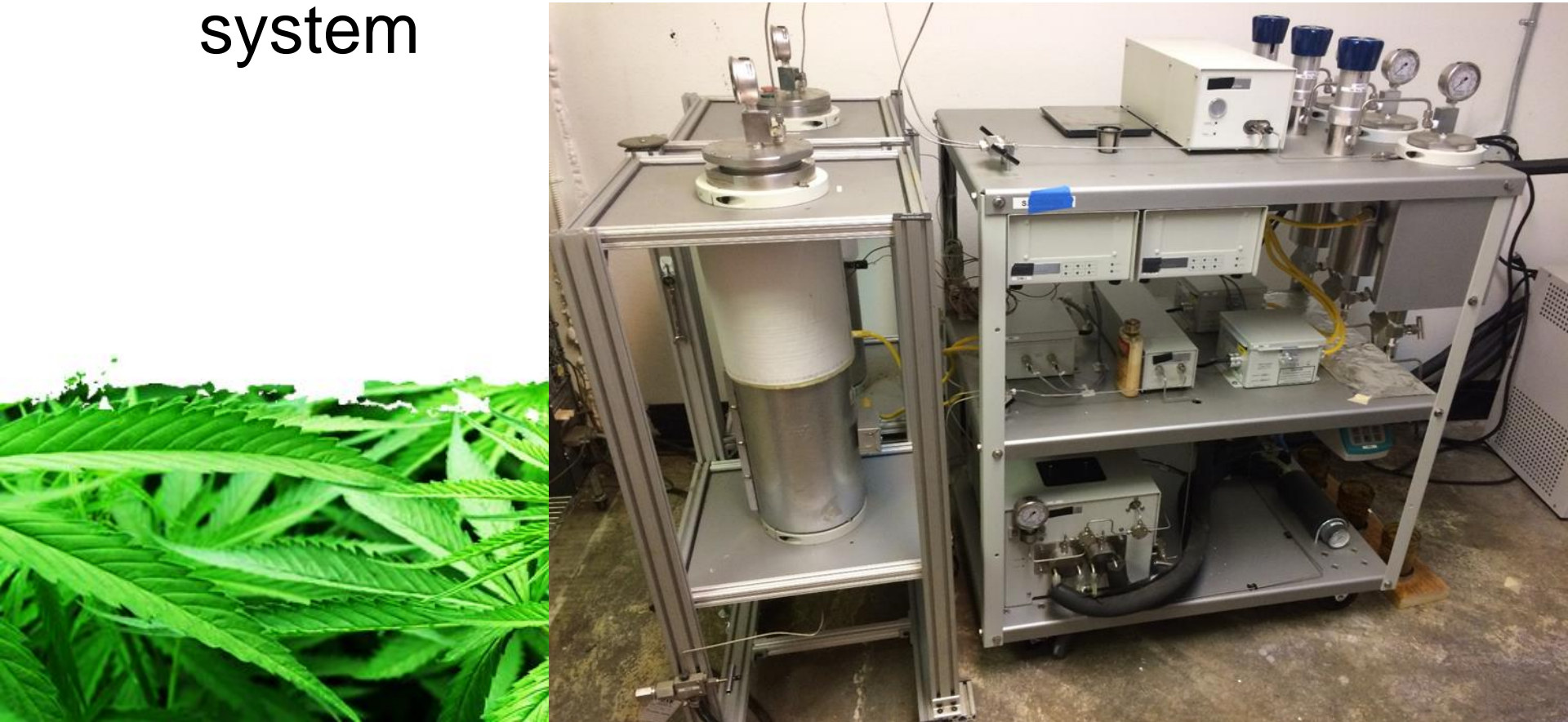


Butter Extraction



Carbon Dioxide Extraction

- This method is very efficient extracting active ingredients by using CO₂ gas in a pressurized system



CO₂ Extraction Unit





CO₂ Extraction

- CO₂ oil Does not leave any chemical residue in the end product
- CO₂ oil, wax, butter, etc.



Butane Extraction

- Butane extraction occurs in a pressurized system, which is passed through buds & leaves to extract THC & CBDs
- This process is one of the most efficient & economical ways to extract active ingredients







Vacuum Unit



Butane Extraction Issues

- Butane extraction may create a fire hazard if not set up and used properly
- Occurrence in Denver:



Butane Extraction Hazards

<https://www.youtube.com/watch?v=agZBqKB>
[Dq_4](#)





Sample ID	Weight (g)	Volume (mL)	Concentration (%)	Notes
101	10.0	10.0	10.0	
102	10.0	10.0	10.0	
103	10.0	10.0	10.0	
104	10.0	10.0	10.0	
105	10.0	10.0	10.0	
106	10.0	10.0	10.0	
107	10.0	10.0	10.0	
108	10.0	10.0	10.0	
109	10.0	10.0	10.0	
110	10.0	10.0	10.0	
111	10.0	10.0	10.0	
112	10.0	10.0	10.0	
113	10.0	10.0	10.0	
114	10.0	10.0	10.0	
115	10.0	10.0	10.0	
116	10.0	10.0	10.0	
117	10.0	10.0	10.0	
118	10.0	10.0	10.0	
119	10.0	10.0	10.0	
120	10.0	10.0	10.0	

RECOMMENDED EQUIPMENT
TARGET ORGANISM
Large, Proteinaceous
Fungi, Bacteria, Viruses

Shatter Run

READY REC: [Signature]

Date Rec'd: [Date]
Tap Weight: [Weight]
Pack Weight: [Weight]
Time in Freezer: [Time]
Final Weight: [Weight]

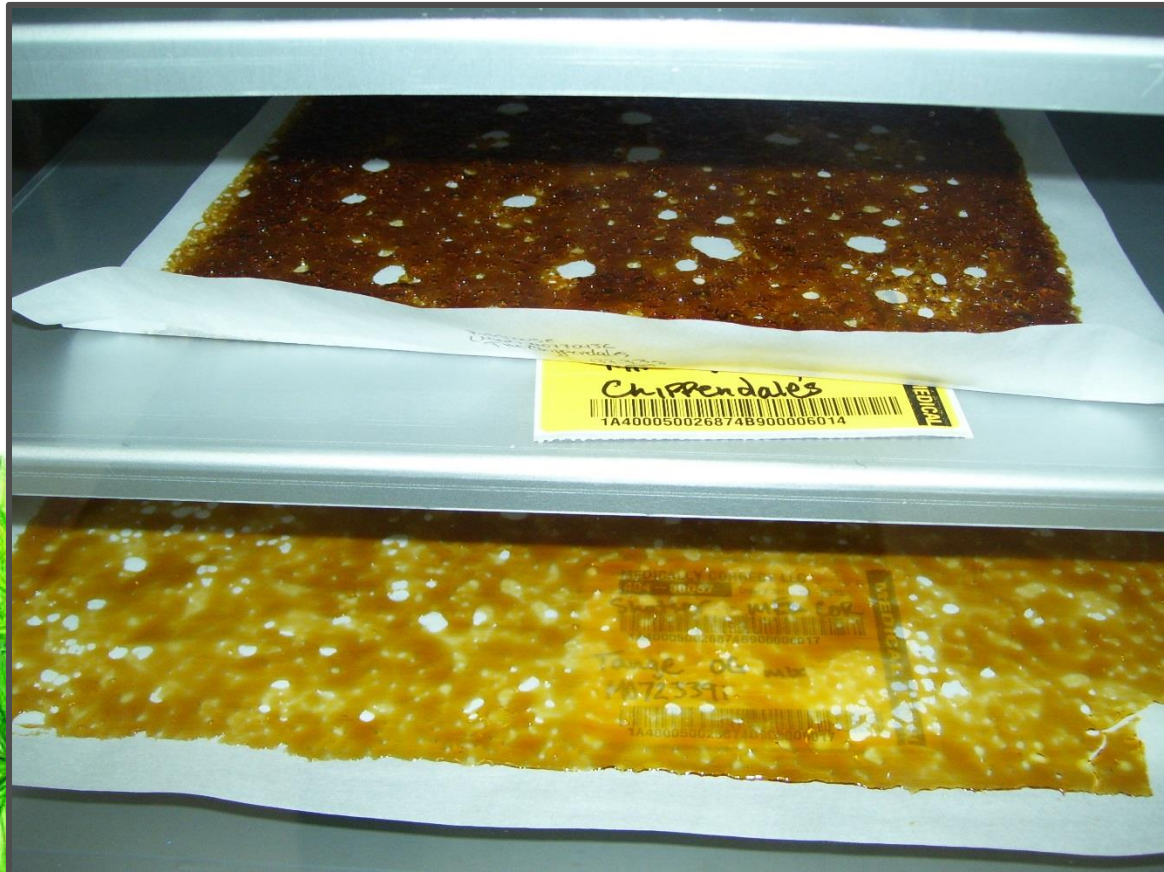
Sample	Weight (g)	Volume (mL)	Concentration (%)
101	10.0	10.0	10.0
102	10.0	10.0	10.0
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105	10.0	10.0	10.0
106	10.0	10.0	10.0
107	10.0	10.0	10.0
108	10.0	10.0	10.0
109	10.0	10.0	10.0
110	10.0	10.0	10.0
111	10.0	10.0	10.0
112	10.0	10.0	10.0
113	10.0	10.0	10.0
114	10.0	10.0	10.0
115	10.0	10.0	10.0
116	10.0	10.0	10.0
117	10.0	10.0	10.0
118	10.0	10.0	10.0
119	10.0	10.0	10.0
120	10.0	10.0	10.0

Chem Used: [Chemical]
Time Adjusted: [Time]
Chem Temp: [Temp]
Notes: [Notes]

Date: [Date]
Time: [Time]
Location: [Location]
Person: [Person]
Title: [Title]
Date Sampled: [Date]

Butane Extraction

- After the product is vacuumed to remove butane the substance is dried creating a product called “shatter”



Alcohol Extraction & Distillation





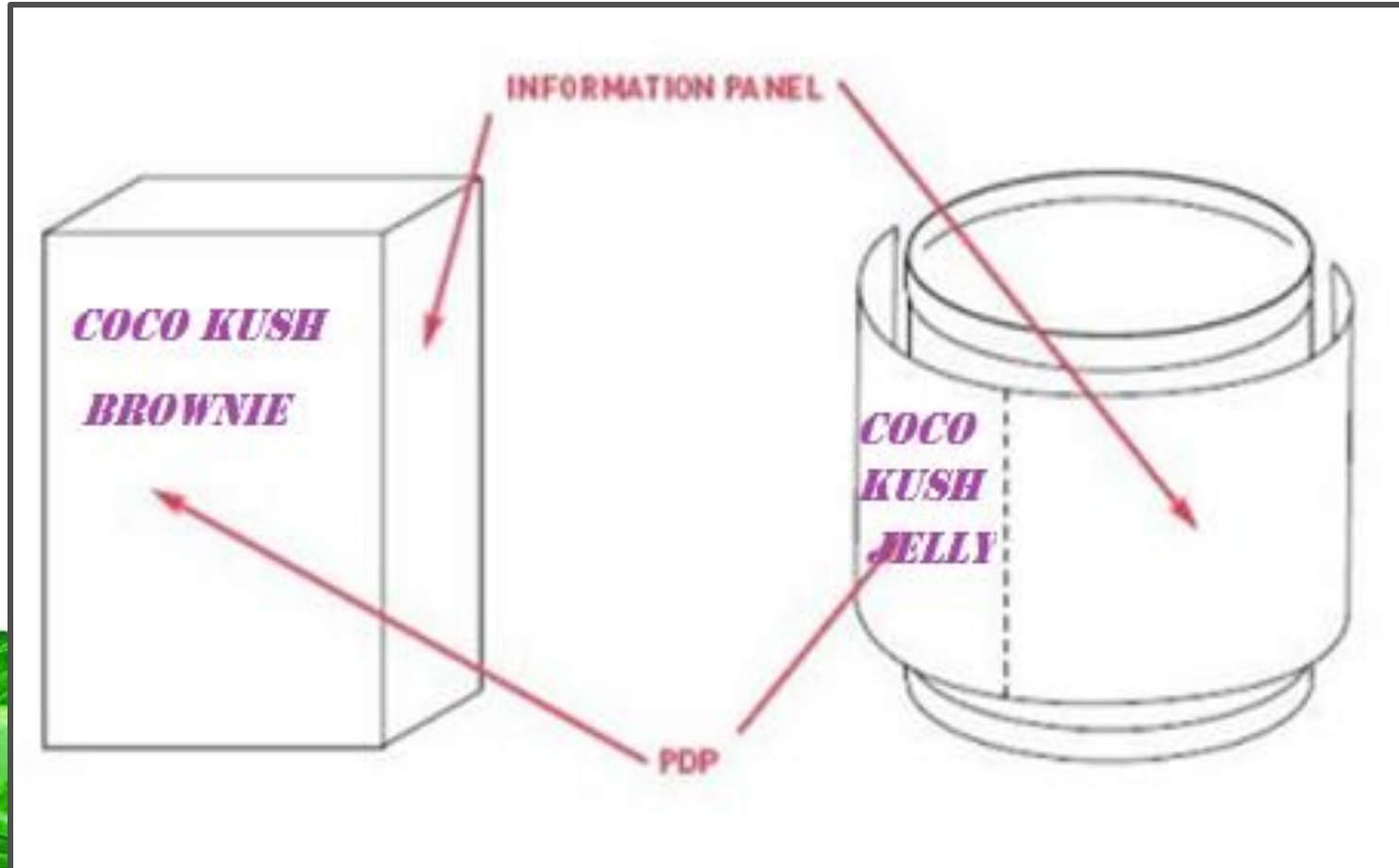
Labeling Guide for Medibles

Borrowed from ADHS, CO, WA, FDA

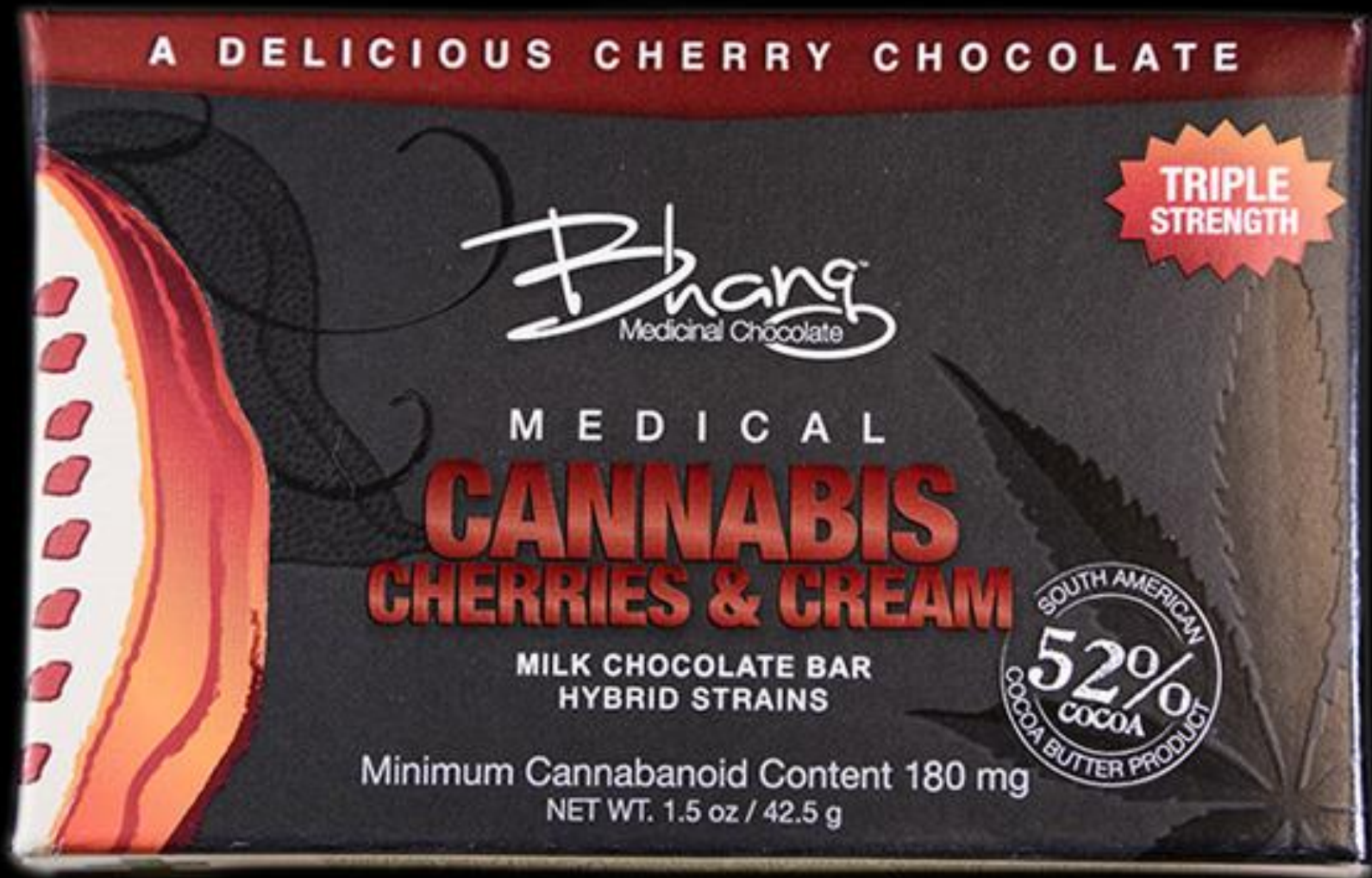
- Active ingredient concentrations on PDP
- Portion control (dosing)
- Information panel
 - Manufacturer information
 - Ingredient & nutrition info
- General Health Warning



Principal Display Panel & Information Panel



Principal Display Panel



Information Panel

INGREDIENTS: MILK CHOCOLATE (SUGAR; MILK; CHOCOLATE; COCO BUTTER; LACTOSE; MILK FAT; SOY LECITHIN; PGRP, EMULSIFIER; VANILLIN, ARTIFICIAL FLAVOR)

GLUTEN FREE. This item is perishable. Keep refrigerated.

Cannabinoid profile per serving:

CBDA	0.3 mg
CBD	20 mg
CBN	4 mg
Δ^9 THC	10 mg
THCA	0mg

The intoxicating effects of this product may be delayed by two or more hours.

The standard Colorado THC dose is 10 mg per serving. This product contains six servings.

There may be health risks associated with the consumption of this product. This product is unlawful outside of the State of Colorado. This product is infused with cannabis. There may be additional health risks associated with the consumption of this product if you are pregnant, breastfeeding, or planning to become pregnant. Do not drive a motor vehicle or operate heavy machinery while using this product. This product has been tested for: mold, mildew, filth, microbes, herbicides, pesticides, fungicides, and harmful chemicals. **KEEP OUT OF THE REACH OF CHILDREN.**

For a complete list of test parameters please visit: [white label client web site.](#)



MANUFACTURED FOR: White label client,
address and contact data.
POWERED BY CLS INC.

How much is in that medible?



Individual Doses

- WA & CO laws require individual doses for edibles,
- Single serving size of 10 mg (WA & CO) with any one single edible not more than 100 mg total (WA).



Warning Label

WARNING!

Do not open container until you have reached your destination.

Do not medicate in parking lot and / or near any public buildings.

Never under any circumstances medicate with any other person(s) not recommended for medical marijuana use by a certified physician.

Do not redistribute your medical cannabis.

Do not operate heavy equipment.

Keep out of reach of children & pets.

Label Examples



Text incredibles to 20300

Cookies Bar

LOT#050R071041

RMCF: 403R-00100

Born: 2/19/2015

EXP: 2/19/2016

Non-organic pesticides: none

THC: 31.02mg THCA: 0.00mg

CBD: 3.39mg CBDA: 0.00mg

CBN: 0.00mg



INGREDIENTS: White Chocolate (sugar; milk, coconut oil, milk fat, lecithin, vanilla), Lab Tested Cannabis, Cookie Sandwich (flour, sugar, leavening, vanilla, cornstarch, chocolate, salt)

Nutrition Facts		Total Fat 6g	3%	Total Carb 10g	6%
		Sat Fat 2g	9%	Fiber 2g	6%
		Trans Fat 0g		Sugar 1g	
Serv. Size 4.5g		Cholest 4mg	1%	Protein 2g	
Serv Per Cont. 10		Sodium 12mg	1%		
Calories 76		Vitamin A 0%	Vitamin C 2%	Calcium 6%	Iron 2%
Fat Cal. 26					

The serving size of active THC in this product is 3mg, this product contains 10 servings of marijuana, and the total amount of active THC in this product is 30mg.

CAUTION: DO NOT CONSUME THIS PRODUCT UNTIL YOU HAVE ADVICE FROM A LICENSED CAREGIVER ON ITS USE AND SIDE EFFECTS. Keep out of reach of children. The marijuana is intended for recreational use solely by the patient to whom it is sold, and that any resale or redistribution of the marijuana to a third person is prohibited. There are no non-organic pesticides, herbicides, and fungicides that were used in the cultivation of the retail marijuana used in the product, unless listed above. This immediate package is considered child resistant. Do not drive a motor vehicle or operate heavy machinery while using marijuana. Solvents used in the extraction concentrate include: n-butane, ethanol. Refrigeration is not necessary but recommended for best quality. This product is infused with marijuana. This product was produced without regulatory oversight for health, safety, or efficacy. The intoxicating effects of this product may be delayed by two or more hours. There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant. The marijuana product contained within this package has not been tested for contaminants. There may be health risks associated with the consumption of this product. This product is intended for use by adults 21 years and older. This product is unlawful outside the State of Colorado. Made in a facility that processes nuts, peanuts, dairy and wheat.



404R-00012



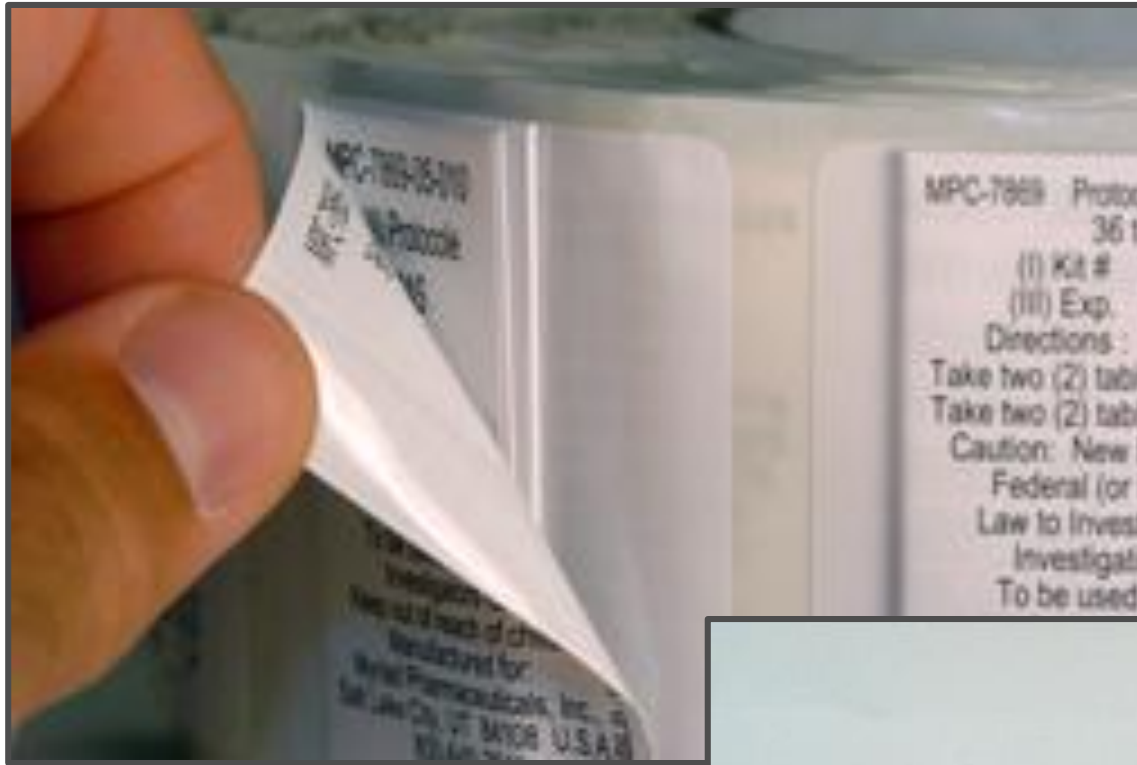
www.MedicallyCorrect.com

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may be unlawful outside the state where purchased. Products containing marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or heavy machinery under the influence of this drug. Caution: When eaten or swallowed, the intoxicating effects of this drug may be delayed by two or more hours. Package patent pending.

Peel-off Labeling



Packaging Guide

- Packaging materials – what's safe?
- Opaque or not?
- Child-resistant – How should it be packaged so it's child-resistant?



Child Resistant Packaging



LAB TESTED
50mg
THC

Cannabis Infused

incredibles

**peanut
Buddha
Buddha**

Peanut Butter Nirvana

NET WEIGHT
45 GRAMS

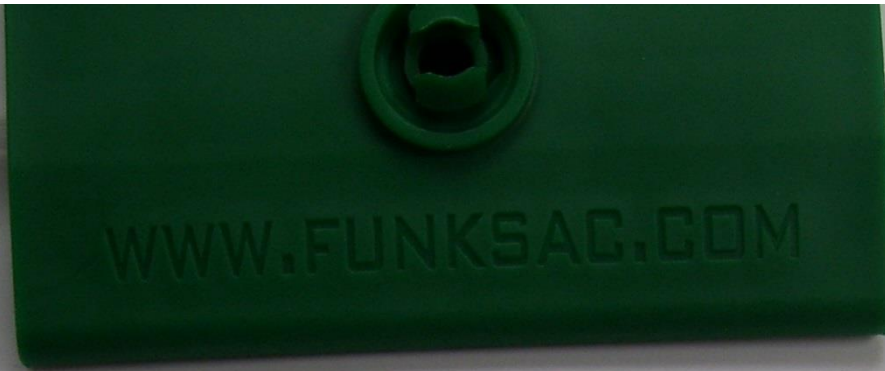
ONLY TO EDUCATE
TAKE 1 BOMBAY IN
MEAT 2 HOURS

incredibles

HIGH-QUALITY HANDCRAFTED INFUSED EDIBLES

incredibles

Child Resistant Packaging



Text Incredibles to 20300
Cookies Bar

LOT#050R071041
RMCF: 403R-00100
Born: 2/19/2015
EXP: 2/19/2016
Non-organic pesticides: none
THC: 31.02mg THCA: 0.00mg
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Nutrition Facts		Total Fat	6g	3%	Total Carb	10g	6%
	Sat Fat	2g	9%	Fiber	2g	6%	
	Trans Fat	0g		Sugar	1g		
Serv. Size	4.5g			Cholest	4mg	1%	Protein
Serv Per Cont.	10			Sodium	12mg	1%	
Calories	76			Vitamin A	0%		Vitamin C
Fat Cal.	26			Vitamin C	2%		Calcium
				Iron	2%		

INGREDIENTS: White Chocolate (sugar; milk, coconut oil, milk fat, lecithin, vanilla), Lab Tested Cannabis, Cookie Sandwich (flour, sugar, leavening, vanilla, cornstarch, chocolate, salt)

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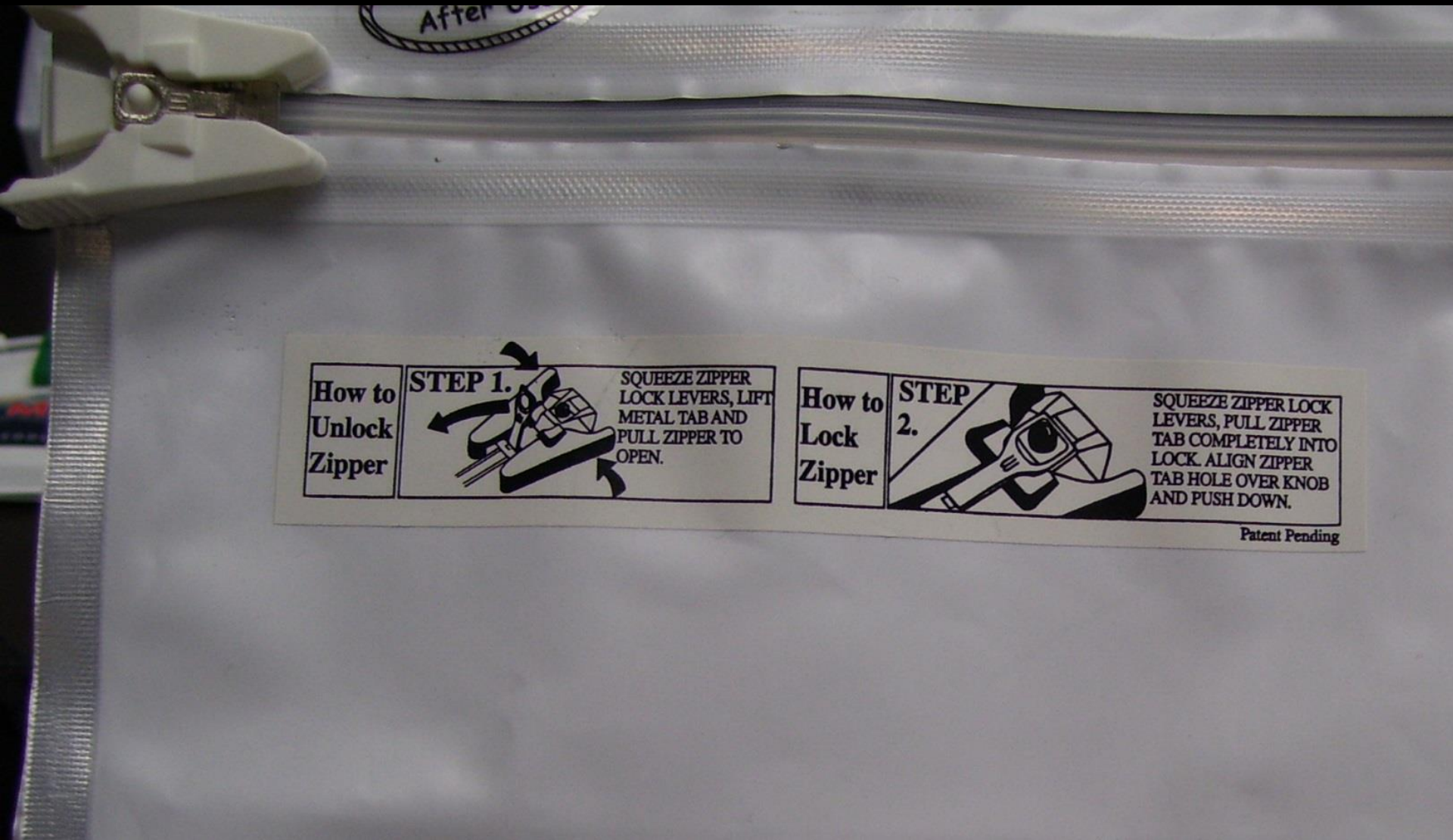
www.MedicallyCorrect.com

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Child Resistant Packaging



**How to
Unlock
Zipper**

STEP 1.



**SQUEEZE ZIPPER
LOCK LEVERS, LIFT
METAL TAB AND
PULL ZIPPER TO
OPEN.**

**How to
Lock
Zipper**

**STEP
2.**



**SQUEEZE ZIPPER LOCK
LEVERS, PULL ZIPPER
TAB COMPLETELY INTO
LOCK. ALIGN ZIPPER
TAB HOLE OVER KNOB
AND PUSH DOWN.**

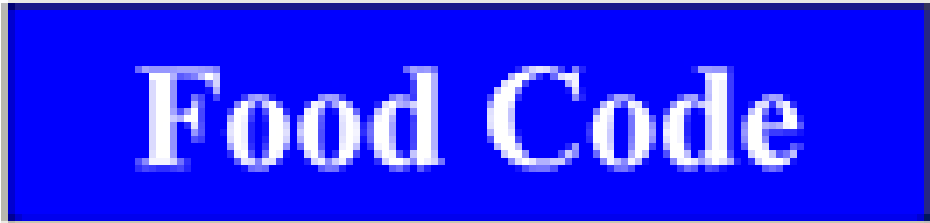
Patent Pending



Food Processing Guide

Borrowed from:

- FDA Current *Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (21 CFR 110)* and
- State Food Code



Food Code

U.S. Public Health Service



Food Processing Draft

- Types of edibles
- Processing controls
- Edible serving size
- Combining active ingredients
- Defective action levels





Medible Types

- Baked goods – brownies, cookies, etc.
- Candies – gummies, hard candy, worms, etc.
- Chocolate bars
- Capsules
- Soda & juice
- Honey
- Cakes & pies
- Powder
- Syringes to inject food
- Tinctures
- Hot sauce, etc...



Edible Processing

- Active ingredient application
- Shelf-life
- Storage – refrigerated or room temp?





Homogenize Active Ingredients



Spray Application of Active Ingredients









Antique & Restored Candy Wrapping Machine



Recall



Testing of Extracts & Medibles

- Not mandated
- No laboratory analysis standards on how to test various medibles

Test for:

- Active ingredients
- Microbial
- Pesticides
- Herbicides
- Solvents



What are safe limits for chemicals?

- Chemicals of concern – butane and hexane (Class 2 solvent) used for extraction
- What are safe limits in edibles?
- Currently, no credible studies have been conducted for residual solvents so rules vary widely:
 - Washington requires 500 ppm butane
 - Colorado went from 50 to 800 ppm
- FDA drug laws do not address butane

Pesticides in Marijuana

- ADHS Code R9-17-317-A-6 requires listing of chemicals, including pesticides (does not mention or require testing for concentration).
- March 2015: Denver Health recalls 100,000 marijuana edibles due to pesticides.
- One plant is worth ~\$1,000
- Five most common pesticides currently banned by Denver Health:
 - ***Myclobutanil*** (Fungicide)
 - ***Imidacloprid*** (Insecticide)
 - ***Abamectin and the avermectin chemical family*** (Insecticide)
 - ***Etoxazo*** (Insecticide)
 - ***Spiromesifen*** (Insecticide)



Survey of Medible Consumers

- Consumers = individuals with prescription from doctor
- Distributed by dispensaries to users
- Electronic survey via Internet
- Medical marijuana edible consumed at least once in past year
- 18 years old +

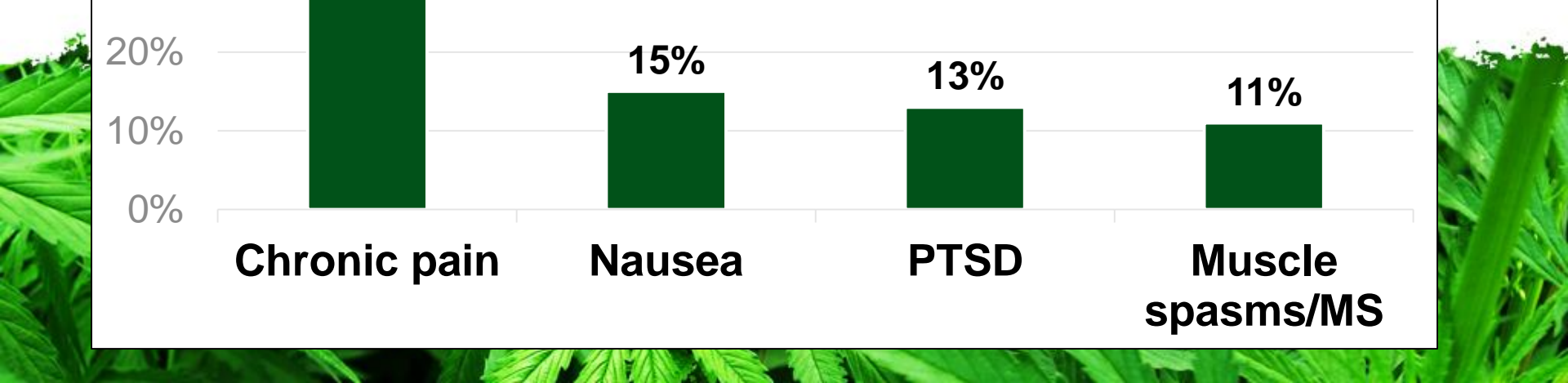
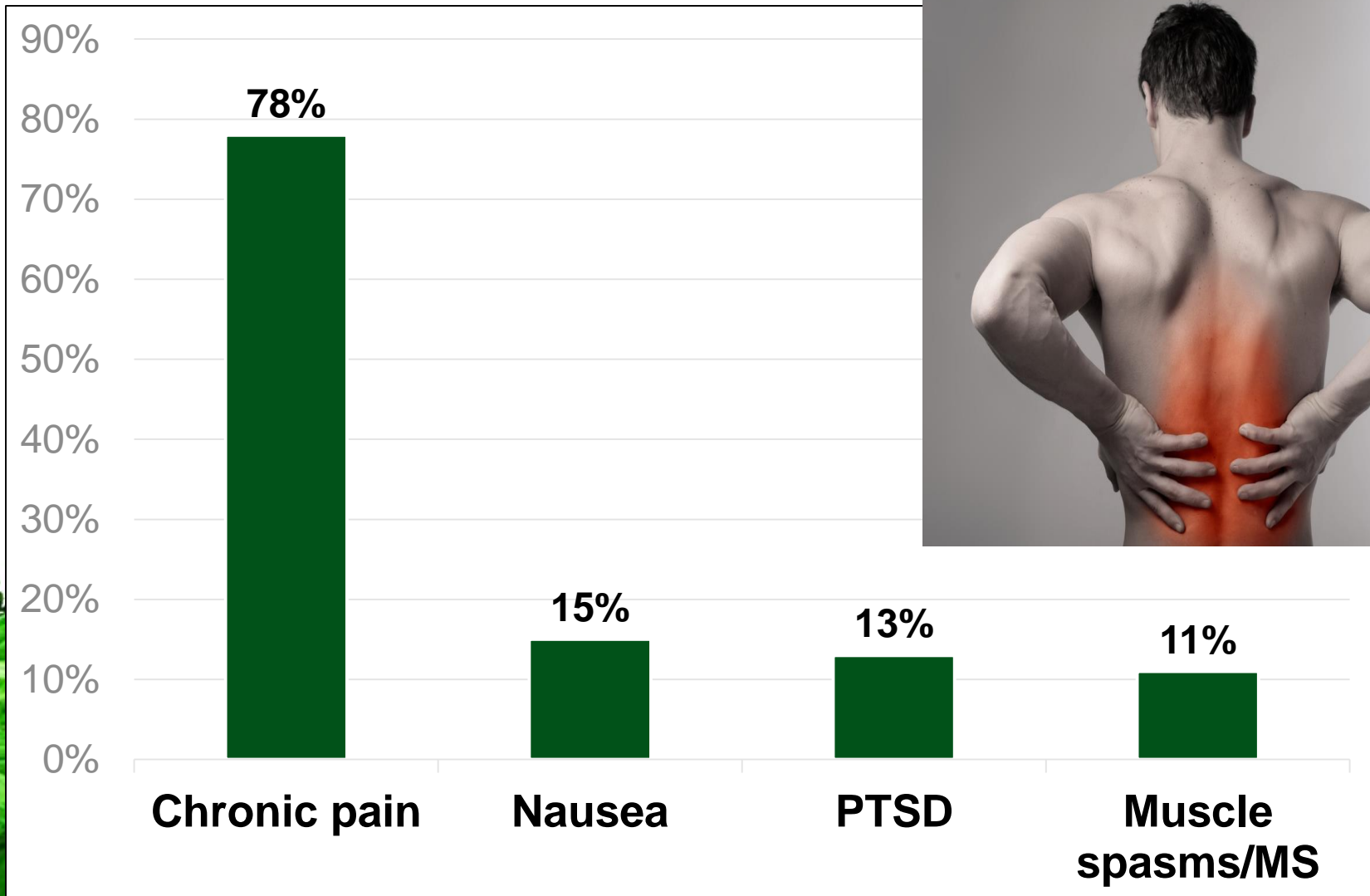


Survey of Medible Consumers

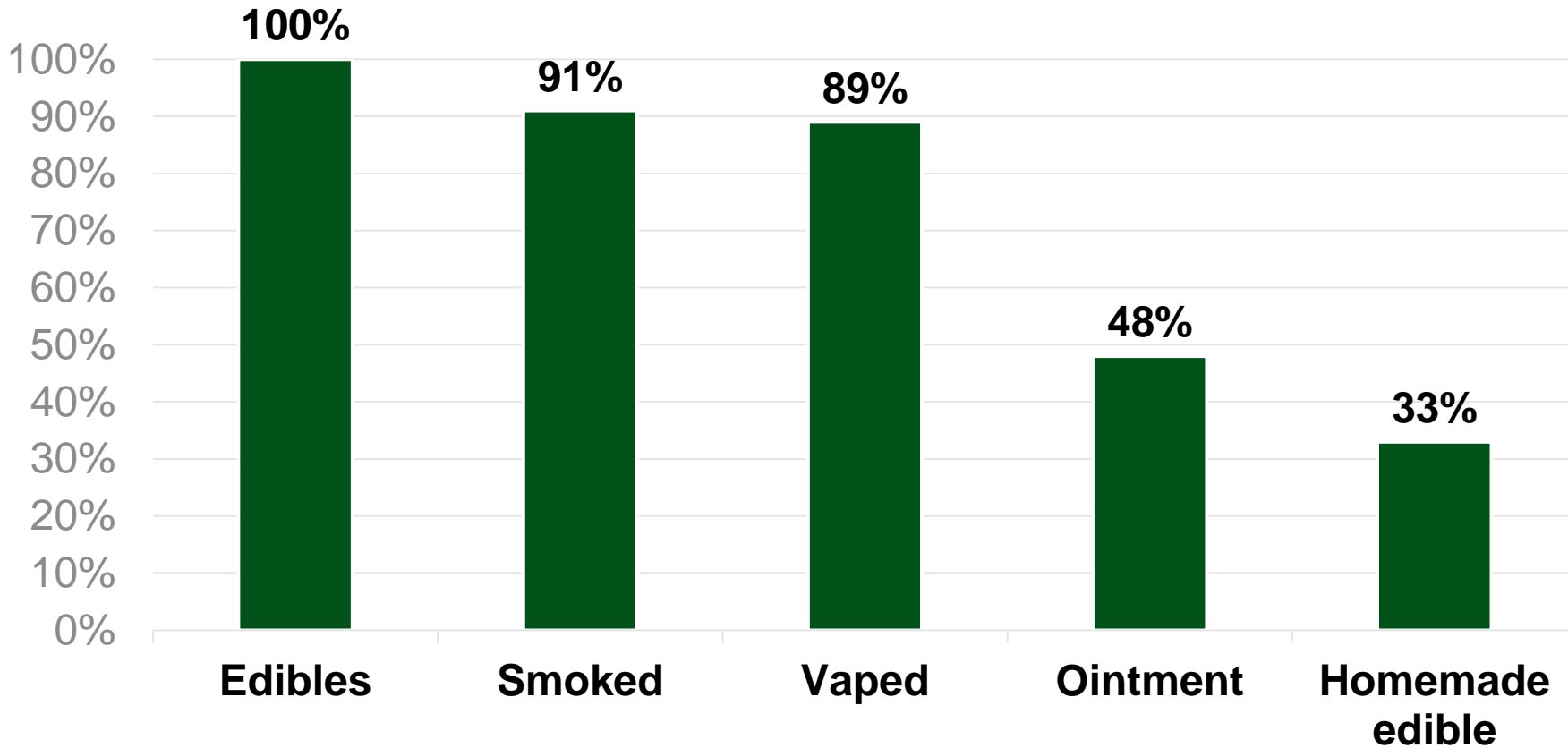
- 46 completed surveys
- Completed March – August 2015
- Questions on usage, labels, frequency consumed, etc.
- Male 58%, female 42%
- Age distribution: 38% (18-34), 30% (35-54) 34% (≥ 55)



Conditions for Which Medibles Used – Mentioned Most Often

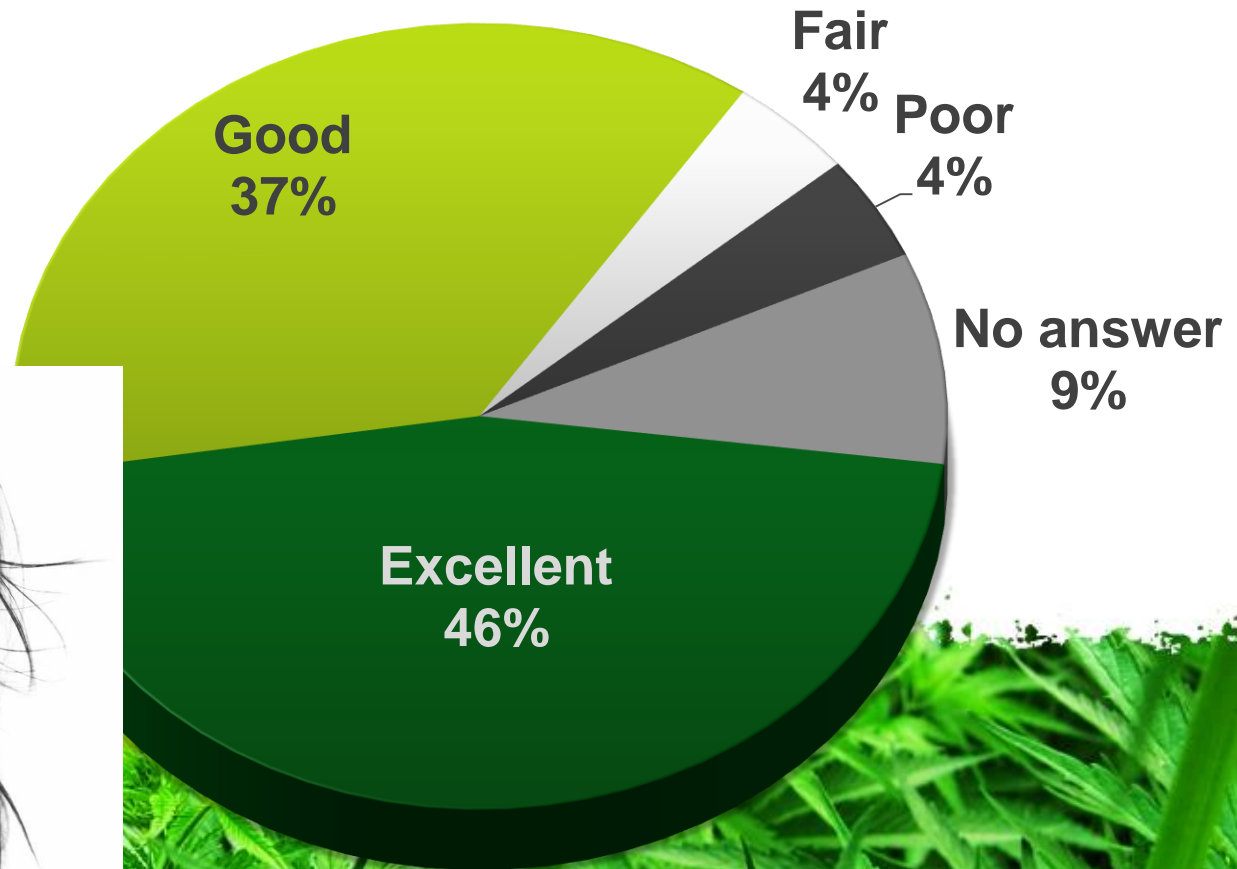


Types Used Past Year



Consumers pleased with MMEs

Effects of MMEs on Condition



Quotes from Respondents

- “They’rrrrrrrrre Great!!!!!! As Tony the Tiger would put it...”
- “They have a place as medicine especially for non-smokers and insomniacs.”
- “Significantly improved my quality of life.”
- “They’re yummy.”



Some Don't Read Label

- 1 in 5 (17%) did not read label last time consumed edible
- 1 in 3 (40%) did not look at grams of marijuana
- 1 in 3 (30%) didn't read instructions included in package

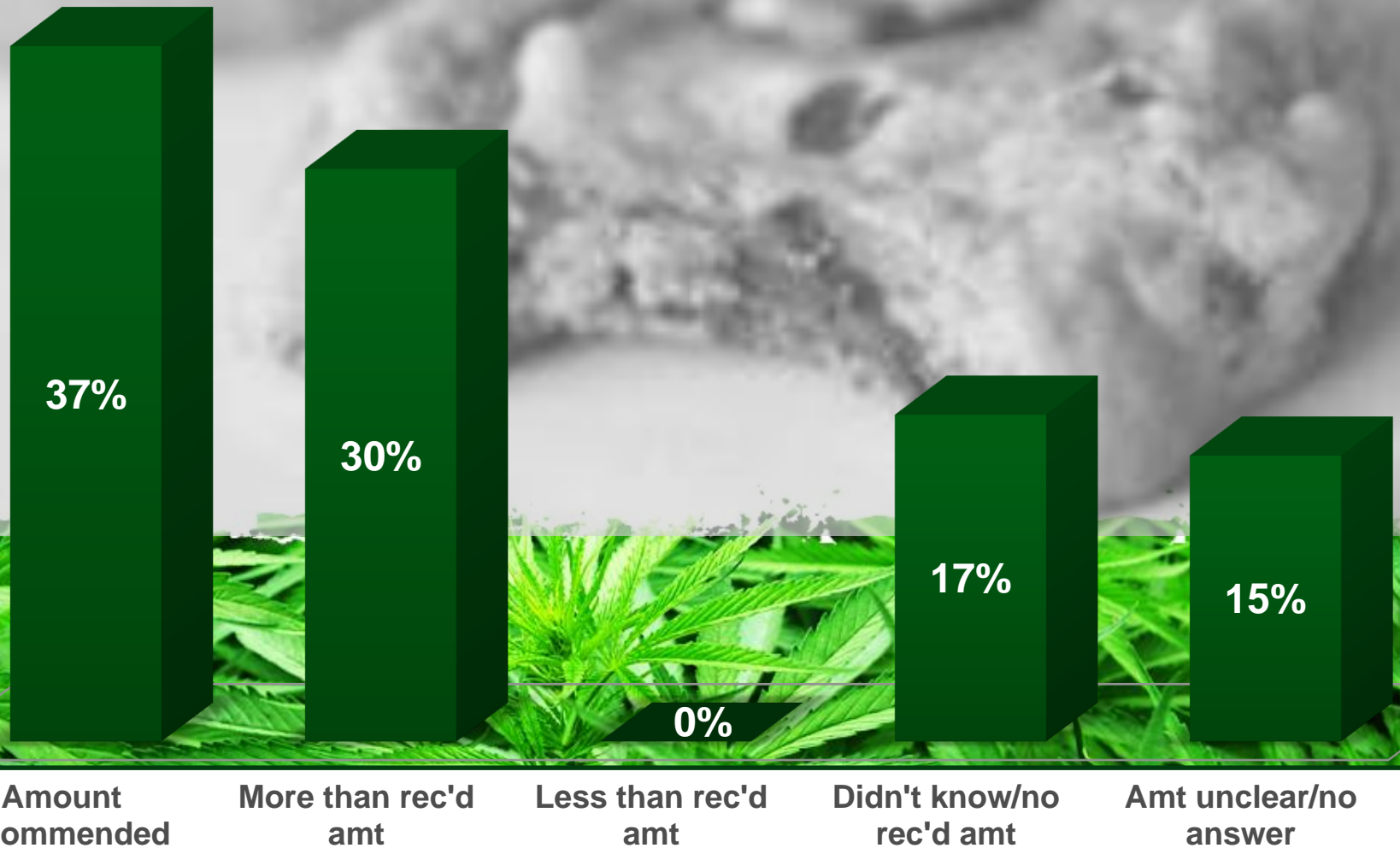


Role of Dispensary Varies

- 46% of respondents said dispensary suggested particular type of MME (raw, consumable, vape pen, etc.)
- 12% said dispensary recommended specific time for how often they should consume edible
 - 41% told as often as needed for symptoms
 - 57% remaining said no recommendation, don't know, or variable frequency



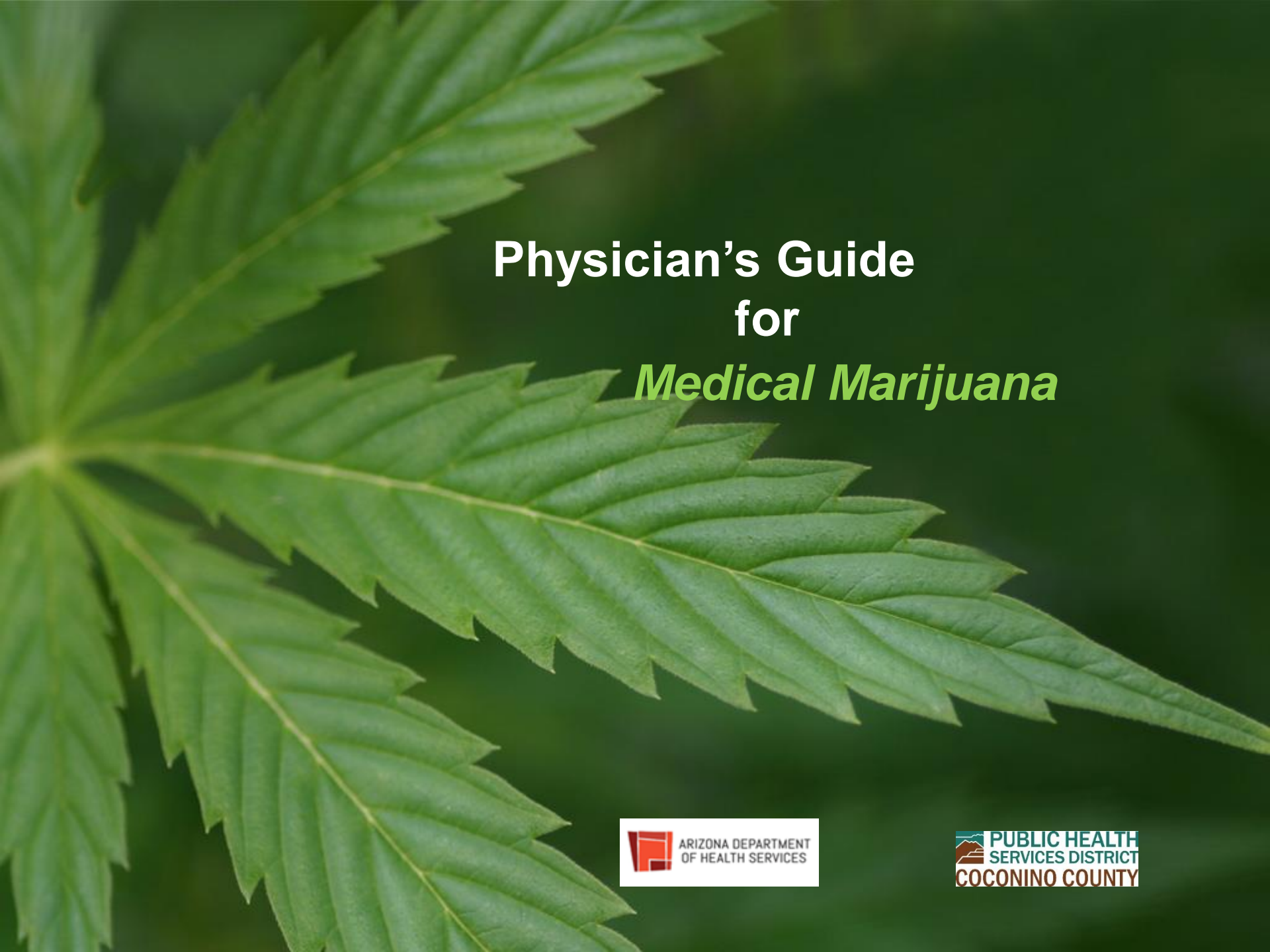
Some consumers use more than recommended amount



What's next?

- Distribute guides to dispensaries after drafts are approved
- Conduct “Bud Tender” Survey and develop best practices for “Bud Tenders”
- Provide presentations to physicians
- Develop best practices for testing edibles





Physician's Guide
for
Medical Marijuana



Special Acknowledgements

- Carla Berg, Special Licensing ADHS
- Wayne Tolbert, Special Licensing ADHS
- John Lick, Special Licensing ADHS
- Various AZ, CO, and WA State Dispensaries who have participated
- Desert Valley Testing and Steve Cottrell
- City of Denver Health Department
- Washington Liquor and Cannabis Board
- Mare Schumacher, CCPHSD



Future Considerations

1. As a potential consumer, what are the three most important components you would like to see included on edible labeling?
2. Should edibles be permitted to look like candy? If “yes”, under what circumstances?
3. Assuming there is a need for standardized training for Bud Tenders (dispensary staff), what topics should be included?



Future Considerations

4. If creating laboratory standards for the testing of marijuana and edibles, what areas would you like to see addressed?

