# CDPH REGULATIONS FOR CANNABIS

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# California Department of Public Health (CDPH)

Role: Protect public health by promoting product and workplace safety



- Oversight of cannabis manufacturers
- Packaging and labeling standards for all cannabis and cannabis products





# LAWS AND REGULATIONS



# **History of Cannabis Law**

Proposition 215: Compassionate Use Act

1996

Proposition 64: Adult Use of Marijuana Act (AUMA)

2016

Permanent Regulations

2019

2015

Medicinal
Cannabis
Regulation and
Safety Act
(MCRSA)

2017

Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA)

Emergency Regulations



## Laws for Cannabis Manufacturers

Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) – Business & Professions Code, Division 10

**CDPH Regulations for Cannabis** 

Other applicable state laws

Applicable local ordinances



# PACKAGING AND LABELING



# Packaging Requirements

- Tamper evident
- Child-resistant
  - During 2019: Can be fulfilled using product package or exit packaging
  - Beginning Jan 1, 2020: Product package must be child resistant
- Resealable (If it has multiple uses)
- Opaque packaging (Edibles only)



## Labeling Requirements

## PARTS OF A LABEL:

## **Primary Panel**

The part of the label most likely to be displayed to the consumer at retail. Typically the front or top of the package

## Informational Panel

Any other part of the label that is not the primary panel



# Labeling Requirements: Cannabis

## **Primary Panel:**

- Product Identity
- Universal Symbol
- Net weight (Metric and US Customary Units)

## Primary OR Informational Panel:

Cannabinoid Content (in %)

## <u>Informational Panel:</u>

- UID Number
- Licensee name & phone number or website (cultivator or packager)
- Date of packaging for retail sale
- Government warning statement



## Labeling Requirements: Cannabis Products

## Primary Panel:

- Product Identity
- Universal Symbol
- Net weight or volume (Metric and US Customary Units)
- "Cannabis-Infused"

## Primary OR Informational Panel:

Cannabinoid Content (in mg)

#### Informational Panel:

- Manufacturer name & website or phone
- Date of manufacture/packaging
- Government warning statement
- UID number
- Batch or lot number
- Instructions for use/any prep needed
- List of ingredients
- Allergens (if applicable)
- Artificial food colorings (if applicable)
- Expiration, use by or best by date (if applicable)
- "KEEP REFRIGERATED" or "REFRIGERATE
   AFTER OPENING" (if perishable after opening)
- "FOR MEDICAL USE ONLY" (if applicable)
- Sodium, sugar, carbohydrates, total fat



## Labeling Requirements: Cannabis Products

### Inner Container Labeling Requirements

\*If the product container is separable from the outer-most packaging

#### For Edibles

Product identity, universal symbol, net weight or volume, "Cannabis-Infused"

For Topicals, Suppositories, Orally-Consumed Concentrates

Product identity, universal symbol, net weight or volume

#### For Inhaled Products

Universal symbol



# **CANNABIS PRODUCTS**



## **Product Classifications**

Edibles

Concentrates

Topicals

Orally-consumed concentrates



## **THC Limits**

## Edibles:

- 10 mg per serving
- 100 mg per package

## Orally-dissolving edibles:

Ex: Lozenges, mouth strips

- 10 mg per serving
- 500 mg per package ("FOR MEDICAL USE ONLY")

## Concentrates, Topicals:

- 1000 mg per package
- 2000 mg per package ("FOR MEDICAL USE ONLY")



# OPERATIONAL REQUIREMENTS



# Good Manufacturing Practices (GMPs)

## Quality Control Program:

- Grounds, building, premises
- Equipment and utensils
- Personnel
- Cannabis product components
- Manufacturing processes and procedures



## **GMP** Documentation

Product Quality Plan (for each product type) – assessment of potential hazards and preventative measures to mitigate risks

Master Manufacturing Protocol (for each formula) – step-by-step instructions that will be used to make the product; "recipe"

Batch Production Records (every time a batch is produced) – documentation of performance

## Record Keeping Requirements

# Standard Operating Procedures (SOPs):

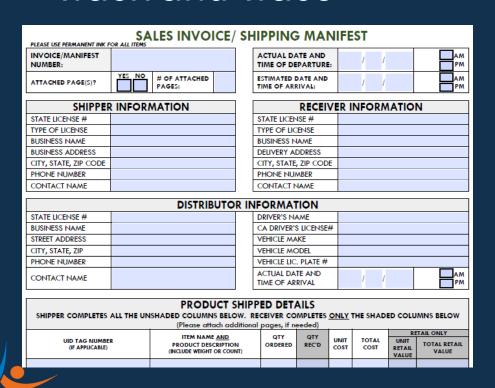
- Security plan
- Emergency response (safety data sheets)
- Track-and-Trace compliance
- Inventory control
- Cannabis waste management
- Personnel training
- Product complaints
- Recalls

- Copies of licenses: CDPH, other state cannabis office, local
- Premises diagram
- Personnel records
- Contracts with other licensees
- Financial records
- Shipping manifests
- Sales invoices/receipts



# Tracking of Cannabis

- Sales invoices and receipts
- Track-and-Trace





# LICENSING OF MANUFACTURERS



# License Types

Type 7 – volatile solvent extraction

Type 6 – non-volatile solvent/ mechanical extraction

Type N – infusion

Type P – packaging and labeling

Shared-use facility registration (with Type 7, 6 or N)

Type S – manufacturers using a shared-use facility



# **Application Process**

Online application: Manufactured Cannabis Licensing System (MCLS)

Individual Information

Business Information Premises Information License Information

\*All "Owners" —

**Business Applicant** 



## License Application Requirements

#### **Individual Information**

Contact information

Live Scan background check

Disclosure of criminal convictions and evidence of rehabilitation

#### **Business Information**

Legal business name

FEIN, seller's permit number, mailing address, primary contact

Disclosure of owners and financial interest holders

Business formation documents

#### **Premises Information**

Premises address

Manufacturing activities

Gross annual revenue

Product types

#### **License Information**

Manufacturing procedures

Premises diagram

Surety bond

Property owner's authorization

Closed-loop certification and fire official approval



# Common Application Questions & Mistakes

Premises Diagrams – Missing details: outline of the premises, boundaries, security camera locations,

SOPs/Descriptions - Incomplete descriptions, purchased SOPs

Closed-Loop System Certifications - Certified as installed, fire official review

Provisional Licenses - Eligibility is assessed during annual license review



# Tips for Applicants

Don't wait until the last minute to submit your application – annuals take time to process

Submit a complete application – incomplete applications cannot be processed

If our team contacts you with requests for information, respond in a timely manner



# Thank you

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