CDPH REGULATIONS FOR CANNABIS

Christina Dempsey
California Department of Public Health
Manufactured Cannabis Safety Branch
California Department of Public Health (CDPH)

Role: Protect public health by promoting product and workplace safety

Manufactured Cannabis Safety Branch

• 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)
- Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) (2017)
- Emergency Regulations
- Permanent Regulations (2019)
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:

<table>
<thead>
<tr>
<th><strong>Primary Panel</strong></th>
<th><strong>Informational Panel</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The part of the label most likely to be displayed to the consumer at retail. Typically the front or top of the package</td>
<td>Any other part of the label that is not the primary panel</td>
</tr>
</tbody>
</table>
Labeling Requirements: Cannabis

Primary Panel:
• Product Identity
• Universal Symbol
• Net weight (Metric and US Customary Units)

Primary OR Informational Panel:
• Cannabinoid Content (*in %*)

Informational Panel:
• 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

Orally-consumed concentrates

Topicals
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”)
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

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**SALES INVOICE / SHIPPING MANIFEST**

<table>
<thead>
<tr>
<th>SHIPPER INFORMATION</th>
<th>RECEIVER INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>STATE LICENSE #</td>
<td>STATE LICENSE #</td>
</tr>
<tr>
<td>TYPE OF LICENSE</td>
<td>TYPE OF LICENSE</td>
</tr>
<tr>
<td>BUSINESS NAME</td>
<td>BUSINESS NAME</td>
</tr>
<tr>
<td>BUSINESS ADDRESS</td>
<td>BUSINESS ADDRESS</td>
</tr>
<tr>
<td>CITY, STATE, ZIP CODE</td>
<td>CITY, STATE, ZIP CODE</td>
</tr>
<tr>
<td>PHONE NUMBER</td>
<td>PHONE NUMBER</td>
</tr>
<tr>
<td>CONTACT NAME</td>
<td>CONTACT NAME</td>
</tr>
</tbody>
</table>

**DISTRIBUTOR INFORMATION**

<table>
<thead>
<tr>
<th>STATE LICENSE #</th>
<th>CA DRIVER'S LICENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUSINESS NAME</td>
<td>DRIVER'S LICENSE</td>
</tr>
<tr>
<td>STREET ADDRESS</td>
<td>VEHICLE MAKE</td>
</tr>
<tr>
<td>CITY, STATE, ZIP</td>
<td>VEHICLE MODEL</td>
</tr>
<tr>
<td>PHONE NUMBER</td>
<td>VEHICLE LIC. PLATE</td>
</tr>
<tr>
<td>CONTACT NAME</td>
<td>TIME OF ARRIVAL</td>
</tr>
</tbody>
</table>

**PRODUCT SHIPPED DETAILS**

<table>
<thead>
<tr>
<th>SHIPPER COMPLETES: ALL THE UNSHADED COLUMNS BELOW. RECEIVER COMPLETES ONLY THE SHADED COLUMNS BELOW (Please attach additional pages, if necessary).</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
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</tbody>
</table>

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California Department of Public Health
Manufactured Cannabis Safety Branch
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)

*All “Owners” →

Individual Information  Business Information  Premises Information  License Information

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