

State of California, Department of Cannabis Control
Licensee Notification and Request Form

Corrective Action Plan For Remediation

This Corrective Action Plan form may be used when cannabis or cannabis product is to be remediated, reprocessed, repackaged, relabeled, reformulated, or modified in any way, pursuant to California Code of Regulations, Title 4, Section 17305.

It is the responsibility of the licensee submitting the Corrective Action Plan to ensure that the activities identified in the plan comply with any other applicable local, state, and federal laws.

If you are the original manufacturer of the product and the product is adulterated, it is your responsibility to ensure that a root cause analysis is conducted to identify the source of the adulterant(s) that caused the test failure, and to incorporate measures to prevent future failures in your product quality plan, pursuant to CCR, Title 4, section 17214.

Use of this form is optional and is intended to assist you in providing a complete description of the how the cannabis product or harvest batch will be remediated so that the cannabis product or harvest batch, or any product produced therefrom, will meet all regulatory compliance testing standards and quality assurance requirements. If you would prefer not to use this form, you can type the information requested in the form directly into an email or provide other documentation supporting your corrective action plan.

The Corrective Action Plan must be approved by the Department prior to beginning any remediation, reprocessing, repackaging, relabeling, reformulation, or modification to the cannabis or cannabis product.

Instructions

Complete all sections of the form.

Include the following attachments:

- Photos of all sides of the packaging and labeling of each batch;
- Material safety data sheets if applicable,

- Any studies referenced in the Corrective Action Plan,
- Documentation that any solvent or materials to be used are food grade,
- Certification for the closed loop extraction system, if one will be used, and
- Any additional supporting documents you would like the department to consider.

The Corrective Action Plan and all attachments must be submitted to remediation@cannabis.ca.gov by the licensee that will perform the remediation, pursuant to CCR, Title 4, section 17305(e).

Department staff may ask for additional documentation on an as needed basis, which may include standard operating procedures, training documents, master manufacturing protocols, product quality plans, and batch production records.

Date of Submission:

LICENSEE INFORMATION

LICENSEE THAT WILL PERFORM THE CORRECTIVE ACTION

Legal Business Name and DBA:

License Number: Premises Address:

Name of Contact Person:

Email Address:

Phone Number:

License Type: Microbusiness Type P Type N Type S Type 6 Type 7 Distributor

LICENSED DISTRIBUTOR CURRENTLY HOLDING THE BATCH

Legal Business Name and DBA:

License Number:

CORRECTIVE ACTION PLAN

Attach additional pages as necessary

1. Describe each step of the proposed remediation method and intent. For failed cannabis or cannabis products only, identify the step(s) in your remediation method that will address the adulterant so that the cannabis, cannabis product, or any product produced therefrom, will meet all regulatory compliance testing standards and quality assurance requirements.
2. For failed cannabis or cannabis products only, describe the scientific support for the remediation activity, or validation studies that you have conducted, demonstrating that this process can adequately address the specific adulterant. Please attach any supporting studies that you reference.

3. List the materials that will be utilized during this remediation, including solvents, reagents, chemicals and/or equipment and describe the purpose for each item. Provide material safety data sheets, certificate of analysis for the solvent(s), closed loop certificate, and local fire code approval to conduct extractions, if required by local ordinance. Pictures of materials may be included, as well as material safety data sheets, and documentation, to support those solvents and other materials are food grade.

4. For all corrective action plans, describe your analysis of any biological, chemical, or physical hazards that may be introduced during the remediation activity and provide details of the preventative measures intended to mitigate those hazards and ensure safety of the final product.

