NEW MEXICO DEPARTMENT OF HEALTH

Medical Cannabis Program Manufacturer Application Cover Page

Application Year: _____

Business Name, DBA: _____

Date application submitted: _____ Application submitted by: _____

Telephone: _____ Email address: _____

Are you an existing Approved Manufacturer? Circle one: **Yes** **or** **No**

Please select the purpose of this application:

- ☐ Independent manufacturer applying for a **new approval**
- ☐ Independent manufacturer applying for renewal
- ☐ LNPP applying for new manufacturing approval (no fee amendment)

Application and Fees (Due Dates and Costs)

An independent manufacturer applicant shall submit an authorized application form to the program with each initial application and at the time of the manufacturer's renewal, together with a fee of one thousand dollars ($1,000) issued to the Medical Cannabis Program. An approved independent manufacturer shall apply for renewal annually no later than 30 days prior to expiration.

Check #: _____ Amount: _____

Money Order #: _____ Amount: _____

LNPPs manufacturing under current approved production plan, shall submit an authorized application form to the program each year at renewal.

Submit Application by Hand Delivery

Submit Binder/written copy and electronic thumb drive to the following address:

New Mexico Department of Health
5301 Central Ave. NE Suite 204
Albuquerque, NM 87108

Note: Incomplete applications will not be processed.

NEW MEXICO DEPARTMENT OF HEALTH

MCP Manufacturing Application

Year: _____

Applicant Information

Manufacturer Name
DBA Business
Name: _____ Date: _____

Address: _____
Street Address *Suite/Unit #*

_____
City *State* *ZIP Code*

Mailing Address: _____ Phone: _____
_____ Phone: _____
_____ Phone: _____

Email: _____
Print name of Owner: _____ Anticipated Open Date: _____

Notice: *Submission of this manufacturer application, does not guarantee approval. Manufacturer may not begin handling medical cannabis products, until the application is approved by the MCP. Manufacturer applications must be submitted annually; approvals are good for 1 year, following final MCP approval, and shall expire after that year, or upon closure of the manufacturer. An approved manufacturer shall apply for renewal of approval annually no later than 30 days prior to expiration. Manufacturer applications will not be considered, nor approved, at the address of a private residence. Submit all contracts, such as Memorandum of Understanding, Memorandum of Agreements and a listing of all entities the Manufacturer will conduct medical cannabis business with. Identification cards issued by the department are the property of the department and shall be returned to the department upon termination of the holder's employment with the approved laboratory, suspension, or revocation of approval by the department, or upon demand of the department.* ***Department regulations are subject to change. It is the responsibility of the applicant and or licensee to familiarize themselves with all current and proposed regulations.***

7.34.4.12 Department Approval of Manufacturers of Cannabis Derived Products; General Provisions:

A. Submittal of applications: A manufacturer applicant shall submit a completed application form to the program with each initial application and each renewal application, together with a fee of one thousand dollars ($1,000) issued to the Medical Cannabis Program. A manufacturer applicant shall comply with the application requirements of Department rule and shall submit such other information as the manufacturer applicant wishes to provide or such information as the department may request for initial approval or periodic evaluation(s) during the approval period.

B. Application requirements: A manufacturer applicant shall submit to the department:

Below are the items needed to satisfy a complete Manufacturer application. Each listed item must be submitted in written and electronic format, simultaneously, in order for the application to be considered complete. Check each box once each item is satisfied and ready to submit to MCP. Submit written copy in a binder with tabs identifying each item. Include electronic jump drive, containing the electronic copy in the binder as well.

☐ **(1)** proof that the manufacturer applicant is in good standing with the New Mexico taxation and revenue department;

☐ **(2)** copies of the manufacturer applicant's articles of incorporation and by-laws, applicable;

☐ **(3)** a complete written description of the means that the manufacturer applicant shall employ to safely manufacture cannabis-derived products, including but not limited to hygiene standards consistent with the requirements of this rule;

☐ **(4)** a list of all persons or business entities having direct or indirect authority over the management or policies of the manufacturer applicant;

☐ **(5)** a list of all persons or business entities having any ownership interest in any property utilized by the manufacturer applicant, whether direct or indirect, and whether the interest is in land, building(s), or other material, including owners of any business entity that owns all or part of land or building(s) utilized;

☐ **(6)** a description of the facilities that shall be used in the manufacture of cannabis derived products;

☐ **(7)** a description of how the manufacturer applicant will obtain cannabis or cannabis concentrates from a licensed non-profit producer, and how the manufacturer applicant will transport cannabis derived products to a licensed non-profit producer, including but not limited to chain of custody documentation;

☐ **(8)** testing criteria and procedures, which shall be consistent with the testing requirements of this rule;

☐ **(9)** a general written security policy, to address at a minimum:

- **(a)** safety and security procedures;
- **(b)** personal safety; and
- **(c)** crime prevention techniques.

☐ **(10)** an attestation that no firearms will be permitted on any premises used for manufacture of cannabis derived products by the manufacturer applicant;

☐ **(11)** a description of the methods and device or series of devices that shall be used to provide security;

☐ **(12)** training documentation prepared for each employee of the manufacturer applicant, statements signed by employees indicating the topics discussed (to include names and titles of presenters) and the date, time, and place the employee received said training;

☐ **(13)** employee policies and procedures to address the following requirements:

- **(a)** job descriptions or employment contracts developed for every employee of the manufacturer applicant that identify duties, authority, responsibilities, qualifications, and supervision; and
- **(b)** training materials concerning adherence to state and federal confidentiality laws.

☐ **(14)** personnel records for each employee of the manufacturer applicant that include an application for employment and a record of any disciplinary action taken;

☐ **(15)** employee safety and security training materials provided to each employee of the manufacturer applicant at the time of his or her initial appointment, to include:

- **(a)** training in the proper use of security measures and controls that have been adopted; and
- **(b)** specific procedural instructions regarding how to respond to an emergency, including robbery or a violent accident.

☐ **(16)** such other materials as the department may require.

The MCP requires each of the following items to be submitted with this application:

- Regulation and Licensing Division LPG Gas approval of use (if applicable)
- Proof that no buildings to be used by the applicant are located within 300 feet of any school, church, or daycare center.

7.34.4.12 NMAC Product Packaging and Labeling (see additional requirements, as per 7.34.4.14 NMAC)

C. Packaging and labeling: The manufacturer applicant attests that it has included within its application a description and sample of the opaque, child resistant packaging of the concentrate or cannabis-derived product that the manufacturer shall utilize. The applicant further attests that the label contains each of the following:

☐ **(1)** the name of the entity that produced the cannabis and the name of the manufacturer;

☐ **(2)** a batch number or code;

☐ **(3)** a production date or expiration date, including a "use by" or "freeze by" date for products capable of supporting the growth of infectious, toxigenic, or spoilage microorganisms;

☐ **(4)** a description of the number of units of usable cannabis contained within the product;

☐ **(5)** instructions for use;

☐ **(6)** warnings for use;

☐ **(7)** instructions for appropriate storage;

☐ **(8)** approved laboratory analysis, including the results of strength and composition within ten percent (10%) of numbers shown on the package;

☐ **(9)** for concentrated cannabis derived product: the quantity of THC and CBD, expressed by weight and by percentage of total weight;

☐ **(10)** the name of the strain, product facts, or a nutrition fact panel, and a statement that the product is for medical use by qualified patients, to be kept away from children, and not for resale;

☐ **(11)** pesticide(s) used in the production of the product; and

☐ **(12)** the name of the department approved testing facility or facilities used for ingredient testing, and the type(s) of testing conducted.

7.34.4.13 STANDARDS FOR MANUFACTURE OF CANNABIS-DERIVED PRODUCTS: **The following are minimum requirements for the manufacture of cannabis-derived products which shall apply to all manufacturers:**

A. General requirements: A licensed non-profit producer and a manufacturer shall take reasonable measures and precautions to ensure the following:

☐ **(1)** That all manufacturing shall be done in premises that are in compliance with local ordinances, including but not limited to zoning, occupancy, licensing, and building codes;

The department requires each of the following items to be submitted with this application:

- Fire Marshall Inspection
- Certificate of Occupancy
- Current Business License Registration
- Zoning Information

Verify each of the following by inserting initials into the corresponding box at the left:

☐ I certify that I will comply with the manufacturing requirements of Department rule 7.34.4 NMAC and any revisions or amendments that are made thereto.

☐ I certify that applications for MCP employee cards are attached, along with photocopies of valid ID or driver license.

☐ I certify that I have attached state and national background check documentation for every person associated with the applicant, including employees, contractors, board members, and persons having direct or indirect authority over management or policies.

☐ I certify that HIPAA training certificates are attached for each person associated with the applicant, including employees.

☐ I certify that employee Food and Safety training certificates are attached.

☐ I certify that I will comply with applicable labeling requirements of Department rule.

☐ I certify that product packaging and label samples are submitted with this application.

☐ I certify that we will not use or be in the possession of dimethylsulfoxide (DMSO) at any time.

Signing below, signifies all material in this MCP Manufacturer application are acknowledged, understood and will be adhered to. All above required documentation will be submitted, simultaneously, with this application. I certify this application is correct and complete to the best of my knowledge.

Performed by:
Manufacturer Representative Signature: _____ Date: _____

Checked by:
Manufacturer Representative Signature: _____ Date: _____

Manufacturer License ID card List

Please attach MCP Employee Identification card request, Department of Public Safety background and national background checks, HIPPA training certificate, copy of driver's license or identification card, and food safety handler certification if applicable. List all employees working for the LNPP or manufacturer on the check list below.

FIRST, LAST NAME	PHOTO ID (Y/N)	STATE BACKGROUND CHECK (Y/N)	FEDERAL BACKGROUND CHECK (Y/N)	HIPAA CERTIFICATION (Y/N)	FOOD HANDLER SAFETY CERTIFICATE (Y/N)	JOB TITLE	LOCATION

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List all Memorandum of Understanding (MOU)

A memorandum of understanding (MOU) is a nonbinding agreement between two or more parties outlining the terms and details of an understanding, including each parties' requirements and responsibilities. An MOU is often the first stage in the formation of a formal contract. Please attach copy of any MOU.

People or Business MOU is with	DATE	EXPIRATION DATE OF MOU (IF APPLICABLE)	REASON FOR MOU

List of All Products Manufactured

Product Name/ Brand	TYPE (FLOWER, EDIBLE, TINCTURE)	PRODUCT USE (TOPICAL, INGESTION, INHALATION, ETC.)

The below section for MCP official use only

Reviewed by:
MCP
Representative
Signature: _____ Date: _____

Checked by:
MCP
Representative
Signature: _____ Date: _____

Application: ☐ **Approved** ☐ **Denied**
reason for denial:

_____

_____

_____

_____

_____

_____

_____

Manufacturer approval given by: _____ on

_____.

Manufacturer expiration date:

_____.