Ohio Medical Marijuana Dispensary Application
OHIO VALLEY WELLNESS LLC.
Application ID 653

Demographic Information(Business Contact)

A-1.1 Business Name, as it appears on the Applicant's certificate of incorporation, charter, bylaws, partnership agreement or other legal business formation documents

OHIO VALLEY WELLNESS LLC.

A-1.2 Other trade names and DBA (doing business as) names

No response provided by applicant

A-1.3 Business Street Address

1561 Pennsylvania Ave.

A-1.4 City

East Liverpool

A-1.5 State

OH

A-1.6 Zip Code

43920

A-1.7 Phone

3302596969

A-1.8 Email

jpicha24@yahoo.com

Demographic Information(Primary Contact/Registered Agent)

A-2.1 Please select: Primary Contact, or Registered Agent for this Application

PRIMARY CONTACT

A-2.2 First Name

JENNIFER

A-2.3 Middle Name

J

A-2.4 Last Name

PICHA

A-2.5 Street Address

2632 HIDDEN CANYON DR

A-2.6 City

BRECKSVILLE

A-2.7 State

OH

A-2.8 Zip Code

44141

A-2.9 Phone

3302596969

A-2.10 Email

jpicha24@yahoo.com

Demographic Information(Applicant Organization and Tax Status)

A-3.1 Select One

Limited Liability Company

A-3.1A If other, explain

No response provided by applicant

A-3.2 State of Incorporation or Registration

OH

A-3.3 Date of Formation

11/09/2017

A-3.4 Business Name on Formation Documents

OHIO VALLEY WELLNESS LLC

A-3.5 Federal Employer ID number

This response has been entirely redacted

A-3.6 Ohio Unemployment Compensation Account Number

No response provided by applicant

A-3.7 Ohio Department of Taxation Number (if Applicant is currently doing business in Ohio)

No response provided by applicant

A-3.8 Ohio Workers' Compensation Policy Number (if Applicant is currently doing business in Ohio)

No response provided by applicant

A-3.9 The Applicant attests that workers' compensation insurance will be obtained by the time the State of Ohio Board of Pharmacy determines the Applicant to be operational under the Act and regulations.

YES

A-3.10 Has the Applicant operated and conducted business in any jurisdiction other than Ohio in the past three years? If you select "**Yes**", answer question A-3.10.1 below.

NO

A-3.10.1 If "**Yes**" to question A-3.10, for each instance relevant to question A-3.10, provide the following:

-Legal Business Name
-Business Address
-Federal Employee ID Number

No response provided by applicant

Demographic Information(Economically Disadvantaged Business)

A-4.1 The Applicant attests that at least fifty-one percent of the business, including corporate stock if a corporation, is owned by persons who belong to one or more of the groups set forth in this division, and that those owners have control over the management and day-to-day operations of the business and an interest in the capital, assets, and profits and losses of the business proportionate to their percentage of ownership. ORC 3796.10

NO

Demographic Information(District Information)

A-5.1 Please select to indicate the medical marijuana dispensary Ohio district for which you are applying for a dispensary license

NORTHEAST-4

A-5.2 Please select to indicate the medical marijuana dispensary Ohio county for which you are applying for a dispensary license

Columbiana

Demographic Information(Prospective Associated Key Employees Details)

Item 1 of 6

A-6.1 First Name

Jennifer

A-6.2 Middle Name

Janell

A-6.3 Last Name

Picha

A-6.4 Suffix

Pharm.D.

A-6.5 Occupation

Pharmacist, Doctor of Pharmacy

A-6.6 Title in the Applicant’s business

President, Chairman of the Board

A-6.7 Applicant's business related compensation

51% after net

A-6.8 Number of shares owned

51/100

A-6.9 Types of shares owned

Common

A-6.10 Percent interest in Applicant's business

41% = contribution to capitol 10% Operations Equity

A-6.11 Voting percentage

25%

A-6.12 Proposed Role

BOARD MEMBER

A-6.13 Please include any contributions of money, equipment, real estate and expertise

Financial Contribution = 51% ($215,000), Expertise Contribution: Employee Training, Inventory

Management, Security and Surveillance, Operations, PharmD

A-6.14 Date of birth

This response has been entirely redacted

A-6.15 Social Security Number (use "N/A" if unavailable)

This response has been entirely redacted

A-6.16 Street Address

2632 Hidden Canyon Drive

A-6.17 City

Brecksville

A-6.18 State

OH

A-6.19 Zip Code

44141

A-6.20 Phone

3302596969

A-6.21 Email

jpicha24@yahoo.com

A-6.22 Race/Ethnicity: (Only answer if applying as an Economically Disadvantaged Business)

No response provided by applicant

A-6.23 If the Prospective Associated Key Employee maintains an Ohio residence, please provide the length of time for which Ohio residency has been established:

38 years - Entire life

A-6.24 Attach verification of identity. The following are acceptable forms of verification of identity:

-Unexpired, valid state-issued driver's license.
-Unexpired, valid photographic identification issued by the Ohio Bureau of Motor Vehicles or the equivalent from another state.
-Unexpired, valid United States passport.

This response has been entirely redacted

A-6.25 Tax Authorization: Each Prospective Associated Key Employee with an aggregate ownership interest of ten percent or more in the Applicant, must print, manually sign and attach a copy of the Tax

Authorization Form. The State Board of Pharmacy may, in its discretion, require an owner or person who exercises substantial control over a proposed dispensary, but who has less than a ten percent ownership interest, to comply with statutory and regulatory ownership requirements. ORC 3796.10, OAC 3796:6-2-02

This response has been entirely redacted

Demographic Information(Prospective Associated Key Employees Details)

Item 2 of 6

A-6.1 First Name

Victor

A-6.2 Middle Name

James

A-6.3 Last Name

Garman

A-6.4 Suffix

n/a

A-6.5 Occupation

Certified Energy Manager, Certified Project Management Professional

A-6.6 Title in the Applicant’s business

Vice President of Operations, Board Member

A-6.7 Applicant's business related compensation

15% of net (distributions)

A-6.8 Number of shares owned

15/100

A-6.9 Types of shares owned

Common

A-6.10 Percent interest in Applicant's business

15%

A-6.11 Voting percentage

25%

A-6.12 Proposed Role

BOARD MEMBER

A-6.13 Please include any contributions of money, equipment, real estate and expertise

Financial Contribution = 15% ($18,775), Expertise Contribution: Regulatory Compliance, Project

Management, Operations, Engineering

A-6.14 Date of birth

This response has been entirely redacted

A-6.15 Social Security Number (use "N/A" if unavailable)

This response has been entirely redacted

A-6.16 Street Address

1050 Ledgestone Dr

A-6.17 City

Folsom

A-6.18 State

CA

A-6.19 Zip Code

95630

A-6.20 Phone

6199911621

A-6.21 Email

registration@torgarman.com

A-6.22 Race/Ethnicity: (Only answer if applying as an Economically Disadvantaged Business)

No response provided by applicant

A-6.23 If the Prospective Associated Key Employee maintains an Ohio residence, please provide the length of time for which Ohio residency has been established:

n/a

A-6.24 Attach verification of identity. The following are acceptable forms of verification of identity:

-Unexpired, valid state-issued driver's license.
-Unexpired, valid photographic identification issued by the Ohio Bureau of Motor Vehicles or the equivalent from another state.
-Unexpired, valid United States passport.

This response has been entirely redacted

A-6.25 Tax Authorization: Each Prospective Associated Key Employee with an aggregate ownership interest of ten percent or more in the Applicant, must print, manually sign and attach a copy of the Tax

Authorization Form. The State Board of Pharmacy may, in its discretion, require an owner or person who exercises substantial control over a proposed dispensary, but who has less than a ten percent ownership interest, to comply with statutory and regulatory ownership requirements. ORC 3796.10, OAC 3796:6-2-02

This response has been entirely redacted

Demographic Information(Prospective Associated Key Employees Details)

Item 3 of 6

A-6.1 First Name

Joseph

A-6.2 Middle Name

Glenn

A-6.3 Last Name

Pappas

A-6.4 Suffix

n/a

A-6.5 Occupation

Business Owner - Jay Pappas, LLC.

A-6.6 Title in the Applicant’s business

CFO - Board Member

A-6.7 Applicant's business related compensation

26% of net (disbursements)

A-6.8 Number of shares owned

26/100

A-6.9 Types of shares owned

Common

A-6.10 Percent interest in Applicant's business

26%

A-6.11 Voting percentage

25%

A-6.12 Proposed Role

BOARD MEMBER

A-6.13 Please include any contributions of money, equipment, real estate and expertise

Financial Contribution = 26% ($162,275), Expertise Contribution: Equity Financing, Corporate Strategy,

Governance

A-6.14 Date of birth

This response has been entirely redacted

A-6.15 Social Security Number (use "N/A" if unavailable)

This response has been entirely redacted

A-6.16 Street Address

3197 Forest Hills Drive

A-6.17 City

East Liverpool

A-6.18 State

OH

A-6.19 Zip Code

43920

A-6.20 Phone

3033832917

A-6.21 Email

jay.pappasoil@gmail.com

A-6.22 Race/Ethnicity: (Only answer if applying as an Economically Disadvantaged Business)

No response provided by applicant

A-6.23 If the Prospective Associated Key Employee maintains an Ohio residence, please provide the length of time for which Ohio residency has been established:

46 years

A-6.24 Attach verification of identity. The following are acceptable forms of verification of identity:

-Unexpired, valid state-issued driver's license.
-Unexpired, valid photographic identification issued by the Ohio Bureau of Motor Vehicles or the equivalent from another state.
-Unexpired, valid United States passport.

This response has been entirely redacted

A-6.25 Tax Authorization: Each Prospective Associated Key Employee with an aggregate ownership interest of ten percent or more in the Applicant, must print, manually sign and attach a copy of the Tax

Authorization Form. The State Board of Pharmacy may, in its discretion, require an owner or person who exercises substantial control over a proposed dispensary, but who has less than a ten percent ownership interest, to comply with statutory and regulatory ownership requirements. ORC 3796.10, OAC 3796:6-2-02

This response has been entirely redacted

Demographic Information(Prospective Associated Key Employees Details)

Item 4 of 6

A-6.1 First Name

Alfonso

A-6.2 Middle Name

Thomas

A-6.3 Last Name

Traina

A-6.4 Suffix

II

A-6.5 Occupation

Executive Vice President Cleanroom Designs LLC

A-6.6 Title in the Applicant’s business

Board Member

A-6.7 Applicant's business related compensation

8% of net (distributions)

A-6.8 Number of shares owned

8/100

A-6.9 Types of shares owned

Common

A-6.10 Percent interest in Applicant's business

8%

A-6.11 Voting percentage

25%

A-6.12 Proposed Role

BOARD MEMBER

A-6.13 Please include any contributions of money, equipment, real estate and expertise

Financial Contribution = 8% ($13,950), Expertise Contribution: Equity Financing, Corporate Strategy,

Governance

A-6.14 Date of birth

This response has been entirely redacted

A-6.15 Social Security Number (use "N/A" if unavailable)

This response has been entirely redacted

A-6.16 Street Address

3930 Americana Drive

A-6.17 City

Tampa

A-6.18 State

FL

A-6.19 Zip Code

33634

A-6.20 Phone

6145469015

A-6.21 Email

atraina24@gmail.com

A-6.22 Race/Ethnicity: (Only answer if applying as an Economically Disadvantaged Business)

No response provided by applicant

A-6.23 If the Prospective Associated Key Employee maintains an Ohio residence, please provide the length of time for which Ohio residency has been established:

n/a

A-6.24 Attach verification of identity. The following are acceptable forms of verification of identity:

-Unexpired, valid state-issued driver's license.
-Unexpired, valid photographic identification issued by the Ohio Bureau of Motor Vehicles or the equivalent from another state.
-Unexpired, valid United States passport.

This response has been entirely redacted

A-6.25 Tax Authorization: Each Prospective Associated Key Employee with an aggregate ownership interest of ten percent or more in the Applicant, must print, manually sign and attach a copy of the Tax

Authorization Form. The State Board of Pharmacy may, in its discretion, require an owner or person who exercises substantial control over a proposed dispensary, but who has less than a ten percent ownership interest, to comply with statutory and regulatory ownership requirements. ORC 3796.10, OAC 3796:6-2-02

No response provided by applicant

Demographic Information(Prospective Associated Key Employees Details)

Item 5 of 6

A-6.1 First Name

Erica

A-6.2 Middle Name

Michelina

A-6.3 Last Name

Graves

A-6.4 Suffix

No response provided by applicant

A-6.5 Occupation

Attorney, Owner California Medical Marijuana Distribution & Processing/Manufacturing facility

A-6.6 Title in the Applicant’s business

Board Member

A-6.7 Applicant's business related compensation

$6000/year for Board responsibilities - To be paid before Net distribution to benificiaries

A-6.8 Number of shares owned

0

A-6.9 Types of shares owned

0

A-6.10 Percent interest in Applicant's business

0%

A-6.11 Voting percentage

0%

A-6.12 Proposed Role

BOARD MEMBER

A-6.13 Please include any contributions of money, equipment, real estate and expertise

Expertise Contribution: Legal, Corporate Strategy, Governance

A-6.14 Date of birth

This response has been entirely redacted

A-6.15 Social Security Number (use "N/A" if unavailable)

This response has been entirely redacted

A-6.16 Street Address

6117 Laird Road

A-6.17 City

Loomis

A-6.18 State

CA

A-6.19 Zip Code

95650

A-6.20 Phone

9163163415

A-6.21 Email

erica@wingparisilaw.com

A-6.22 Race/Ethnicity: (Only answer if applying as an Economically Disadvantaged Business)

No response provided by applicant

A-6.23 If the Prospective Associated Key Employee maintains an Ohio residence, please provide the length of time for which Ohio residency has been established:

n/a

A-6.24 Attach verification of identity. The following are acceptable forms of verification of identity:

-Unexpired, valid state-issued driver's license.
-Unexpired, valid photographic identification issued by the Ohio Bureau of Motor Vehicles or the equivalent from another state.
-Unexpired, valid United States passport.

This response has been entirely redacted

A-6.25 Tax Authorization: Each Prospective Associated Key Employee with an aggregate ownership interest of ten percent or more in the Applicant, must print, manually sign and attach a copy of the Tax Authorization Form. The State Board of Pharmacy may, in its discretion, require an owner or person who exercises substantial control over a proposed dispensary, but who has less than a ten percent

ownership interest, to comply with statutory and regulatory ownership requirements. ORC 3796.10, OAC 3796:6-2-02

No response provided by applicant

Demographic Information(Prospective Associated Key Employees Details)

Item 6 of 6

A-6.1 First Name

Willis

A-6.2 Middle Name

Clark

A-6.3 Last Name

Triplett

A-6.4 Suffix

Pharm.D.

A-6.5 Occupation

Doctor of Pharmacy

A-6.6 Title in the Applicant’s business

Key Employee

A-6.7 Applicant's business related compensation

$6,000/year for professional services as needed

A-6.8 Number of shares owned

0

A-6.9 Types of shares owned

n/a

A-6.10 Percent interest in Applicant's business

0%

A-6.11 Voting percentage

0%

A-6.12 Proposed Role

OTHER

A-6.13 Please include any contributions of money, equipment, real estate and expertise

Expertise Contributions: Doctor of Pharmacy, Quality Assurance, Continuous Improvement, USP

797/800

A-6.14 Date of birth

This response has been entirely redacted

A-6.15 Social Security Number (use "N/A" if unavailable)

This response has been entirely redacted

A-6.16 Street Address

20 Waterford Ct.

A-6.17 City

Zionsville

A-6.18 State

IN

A-6.19 Zip Code

46077

A-6.20 Phone

3176266973

A-6.21 Email

willis.triplett@comply797.com

A-6.22 Race/Ethnicity: (Only answer if applying as an Economically Disadvantaged Business)

No response provided by applicant

A-6.23 If the Prospective Associated Key Employee maintains an Ohio residence, please provide the length of time for which Ohio residency has been established:

n/a

A-6.24 Attach verification of identity. The following are acceptable forms of verification of identity:

-Unexpired, valid state-issued driver's license.
-Unexpired, valid photographic identification issued by the Ohio Bureau of Motor Vehicles or the equivalent from another state.
-Unexpired, valid United States passport.

This response has been entirely redacted

A-6.25 Tax Authorization: Each Prospective Associated Key Employee with an aggregate ownership interest of ten percent or more in the Applicant, must print, manually sign and attach a copy of the Tax

Authorization Form. The State Board of Pharmacy may, in its discretion, require an owner or person who exercises substantial control over a proposed dispensary, but who has less than a ten percent ownership interest, to comply with statutory and regulatory ownership requirements. ORC 3796.10, OAC 3796:6-2-02

No response provided by applicant

Compliance(Compliance with Applicable Laws and Regulations)

B-1.1 By selecting “Yes”, the Applicant, as well as all individually identified Prospective Associated Key Employees listed in this provisional license application, agree to comply with all applicable Ohio laws and regulations relating to the operation of a medical marijuana dispensary.

YES

B-1.2 By selecting “Yes”, the Applicant understands and attests that it must establish and maintain an escrow account or surety bond in the amount of $50,000 as a condition precedent to receiving a medical marijuana certificate of operation. OAC 3796:6-2-11

YES

Compliance(Civil and Administrative Action)

B-2.1 Has the Applicant been the subject of an action resulting in sanctions, disciplinary actions or civil monetary penalties or fines being imposed relating to a registration, license, provisional license or any other authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-2.2 Has the Applicant been the subject of a civil or administrative action relating to a registration, license, provisional license or authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-2.3 Has criminal, civil, or administrative action been taken against the Applicant for obtaining a registration, license, provisional license or other authorization to operate as a cultivator, processor, or dispensary of medical marijuana in any jurisdiction by fraud, misrepresentation, or the submission of false information?

NO

B-2.4 Has criminal, civil or administrative action been taken against the Applicant under the laws of Ohio or any other state, the United States or a military, territorial or tribal authority, relating to any of the Applicant's Prospective Associated Key Employees' profession or occupation?

NO

B-2.4.1 If "**Yes**" to any question in B-2, provide the following: Respondent / Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved, and the Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

Compliance(Prospective Associated Key Employee Compliance)

Item 1 of 6

B-3.1 First Name

Jennifer

B-3.2 Middle Name

Janell

B-3.3 Last Name

Picha

B-3.4 Proposed Role

OWNER

B-3.5 Position/Title

President/Chairman of the Board

B-3.6 Brief description of role

Majority Shareholder. Responsible for Employee Training, Inventory Management, Security and Surveillance, Operations, Compliance, Pharmacy Standards

B-3.7 Has this individual served, or are they currently serving as an owner, officer, or board member of another medical marijuana entity in Ohio or the United States?

NO

B-3.7.1 If "**Yes**" to B-3.7, please provide the entity Name and Address.

n/a

B-3.8 Has this individual had ownership or financial interest, or do they currently have ownership or financial interest of another medical marijuana entity in Ohio or the United States?

NO

B-3.8.1 If "**Yes**" to B-3.8, please provide the entity Name and Address.

n/a

B-3.9 Has this individual ever been convicted of, or are charges pending for, a disqualifying offense? Include instances in which a court granted intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC, or TLC), or other diversion programs. Offenses must be reported regardless of whether the case has been sealed, as described in section 2953.32 of the Revised Code, or the equivalent thereof in another jurisdiction.

NO

B-3.9.1 If "**Yes**" to B-3.9, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.10 Has the individual ever been convicted of, or are charges pending for, any other felony offense under state or federal law?

NO

B-3.10.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.11 Has the individual ever been convicted of, or are charges pending for, a crime (felony or misdemeanor) involving an act of moral turpitude?

NO

B-3.11.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.12 Has this individual ever been disciplined by the State of Ohio Board of Pharmacy or any other licensing body.

NO

B-3.12.1 If "**Yes**", please provide the following: Name, Name and Address of Licensing Board, License Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved

n/a

B-3.13 Has the individual ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is such action pending?

NO

B-3.13.1 If "**Yes**" to B-3.13, the reason for doing so must be provided below.

n/a

B-3.14 Has the individual ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the surrender, suspension, revocation, or probation of the individual's license or registration?

NO

B-3.14.1 If "**Yes**" to B-3.14, the reason for doing so must be provided below.

n/a

B-3.15 Has the individual ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state jurisdiction that was based in whole or in part, on the Applicant's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

NO

B-3.15.1 If "**Yes**" to B-3.15, the reason for doing so must be provided below.

n/a

B-3.16 By selecting "**Yes**", this individual agrees to be enrolled in the Retained Applicant Fingerprint Database (Rapback) should the Applicant be awarded a provisional license.

YES

B-3.17 Has the individual been the subject of an action resulting in sanctions, disciplinary actions or civil monetary penalties being imposed relating to a registration, license, provisional license or any other authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.17.1 If "**Yes**" to B-3.17, the reason for doing so must be provided below.

n/a

B-3.18 Has the individual been the subject of a civil or administrative action relating to a registration, license, provisional license or authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.18.1 If "**Yes**" to B-3.18, the reason for doing so must be provided below.

n/a

B-3.19 Has the individual been accused of obtaining a registration, license, provisional license or other authorization to operate as a cultivator, processor, or dispensary of medical marijuana in any jurisdiction by fraud, misrepresentation, or the submission of false information?

NO

B-3.19.1 If "**Yes**" to B-3.19, the reason for doing so must be provided below.

n/a

B-3.20 Has civil or administrative action been taken against the individual under the laws of Ohio or any other state, the United States or a military, territorial or tribal authority, relating to the individual's profession or occupation?

NO

B-3.20.1 If "**Yes**" to B-3.20, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.21 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees are a physician who has a certificate to recommend medical marijuana or who has applied for a certificate to recommend medical marijuana under section 4731.30 of the Revised Code.

YES

B-3.22 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees have ownership, investment interest, or a compensation arrangement with a laboratory licensed under Chapter 3796 of the Revised Code or an Applicant for a license to conduct laboratory testing.

YES

Compliance(Prospective Associated Key Employee Compliance)

Item 2 of 6

B-3.1 First Name

Victor

B-3.2 Middle Name

James

B-3.3 Last Name

Garman

B-3.4 Proposed Role

PERSON WITH FINANCIAL INTEREST

B-3.5 Position/Title

Vice President of Operations

B-3.6 Brief description of role

Responsible for overseeing operations, establishing processes, procedures, IT systems, Security, Website

B-3.7 Has this individual served, or are they currently serving as an owner, officer, or board member of another medical marijuana entity in Ohio or the United States?

NO

B-3.7.1 If "**Yes**" to B-3.7, please provide the entity Name and Address.

n/a

B-3.8 Has this individual had ownership or financial interest, or do they currently have ownership or financial interest of another medical marijuana entity in Ohio or the United States?

NO

B-3.8.1 If "**Yes**" to B-3.8, please provide the entity Name and Address.

n/a

B-3.9 Has this individual ever been convicted of, or are charges pending for, a disqualifying offense? Include instances in which a court granted intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC, or TLC), or other diversion programs. Offenses must be reported regardless of whether the case has been sealed, as described in section 2953.32 of the Revised Code, or the equivalent thereof in another jurisdiction.

NO

B-3.9.1 If "**Yes**" to B-3.9, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.10 Has the individual ever been convicted of, or are charges pending for, any other felony offense under state or federal law?

NO

B-3.10.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.11 Has the individual ever been convicted of, or are charges pending for, a crime (felony or misdemeanor) involving an act of moral turpitude?

NO

B-3.11.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.12 Has this individual ever been disciplined by the State of Ohio Board of Pharmacy or any other licensing body.

NO

B-3.12.1 If "**Yes**", please provide the following: Name, Name and Address of Licensing Board, License Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved

n/a

B-3.13 Has the individual ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is such action pending?

NO

B-3.13.1 If "**Yes**" to B-3.13, the reason for doing so must be provided below.

n/a

B-3.14 Has the individual ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the surrender, suspension, revocation, or probation of the individual's license or registration?

NO

B-3.14.1 If "**Yes**" to B-3.14, the reason for doing so must be provided below.

n/a

B-3.15 Has the individual ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state jurisdiction that was based in whole or in part, on the Applicant's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

NO

B-3.15.1 If "**Yes**" to B-3.15, the reason for doing so must be provided below.

n/a

B-3.16 By selecting "**Yes**", this individual agrees to be enrolled in the Retained Applicant Fingerprint Database (Rapback) should the Applicant be awarded a provisional license.

YES

B-3.17 Has the individual been the subject of an action resulting in sanctions, disciplinary actions or civil monetary penalties being imposed relating to a registration, license, provisional license or any other authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.17.1 If "**Yes**" to B-3.17, the reason for doing so must be provided below.

n/a

B-3.18 Has the individual been the subject of a civil or administrative action relating to a registration, license, provisional license or authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.18.1 If "**Yes**" to B-3.18, the reason for doing so must be provided below.

n/a

B-3.19 Has the individual been accused of obtaining a registration, license, provisional license or other authorization to operate as a cultivator, processor, or dispensary of medical marijuana in any jurisdiction by fraud, misrepresentation, or the submission of false information?

NO

B-3.19.1 If "**Yes**" to B-3.19, the reason for doing so must be provided below.

n/a

B-3.20 Has civil or administrative action been taken against the individual under the laws of Ohio or any other state, the United States or a military, territorial or tribal authority, relating to the individual's profession or occupation?

NO

B-3.20.1 If "**Yes**" to B-3.20, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.21 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees are a physician who has a certificate to recommend medical marijuana or who has applied for a certificate to recommend medical marijuana under section 4731.30 of the Revised Code.

YES

B-3.22 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees have ownership, investment interest, or a compensation arrangement with a laboratory licensed under Chapter 3796 of the Revised Code or an Applicant for a license to conduct laboratory testing.

YES

Compliance(Prospective Associated Key Employee Compliance)

Item 3 of 6

B-3.1 First Name

Joseph

B-3.2 Middle Name

Glenn

B-3.3 Last Name

Pappas

B-3.4 Proposed Role

PERSON WITH FINANCIAL INTEREST

B-3.5 Position/Title

CFO/Board Member

B-3.6 Brief description of role

Responsible for Corporate Strategy, Governance, Equity, and Financing

B-3.7 Has this individual served, or are they currently serving as an owner, officer, or board member of another medical marijuana entity in Ohio or the United States?

NO

B-3.7.1 If "**Yes**" to B-3.7, please provide the entity Name and Address.

n/a

B-3.8 Has this individual had ownership or financial interest, or do they currently have ownership or financial interest of another medical marijuana entity in Ohio or the United States?

NO

B-3.8.1 If "**Yes**" to B-3.8, please provide the entity Name and Address.

n/a

B-3.9 Has this individual ever been convicted of, or are charges pending for, a disqualifying offense? Include instances in which a court granted intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC, or TLC), or other diversion programs. Offenses must be reported regardless of whether the case has been sealed, as described in section 2953.32 of the Revised Code, or the equivalent thereof in another jurisdiction.

NO

B-3.9.1 If "**Yes**" to B-3.9, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.10 Has the individual ever been convicted of, or are charges pending for, any other felony offense under state or federal law?

NO

B-3.10.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.11 Has the individual ever been convicted of, or are charges pending for, a crime (felony or misdemeanor) involving an act of moral turpitude?

NO

B-3.11.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.12 Has this individual ever been disciplined by the State of Ohio Board of Pharmacy or any other licensing body.

NO

B-3.12.1 If "**Yes**", please provide the following: Name, Name and Address of Licensing Board, License Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved

n/a

B-3.13 Has the individual ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is such action pending?

NO

B-3.13.1 If "**Yes**" to B-3.13, the reason for doing so must be provided below.

n/a

B-3.14 Has the individual ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the surrender, suspension, revocation, or probation of the individual's license or registration?

NO

B-3.14.1 If "**Yes**" to B-3.14, the reason for doing so must be provided below.

n/a

B-3.15 Has the individual ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state jurisdiction that was based in whole or in part, on the Applicant's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

NO

B-3.15.1 If "**Yes**" to B-3.15, the reason for doing so must be provided below.

n/a

B-3.16 By selecting "**Yes**", this individual agrees to be enrolled in the Retained Applicant Fingerprint Database (Rapback) should the Applicant be awarded a provisional license.

YES

B-3.17 Has the individual been the subject of an action resulting in sanctions, disciplinary actions or civil monetary penalties being imposed relating to a registration, license, provisional license or any other authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.17.1 If "**Yes**" to B-3.17, the reason for doing so must be provided below.

n/a

B-3.18 Has the individual been the subject of a civil or administrative action relating to a registration, license, provisional license or authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.18.1 If "**Yes**" to B-3.18, the reason for doing so must be provided below.

n/a

B-3.19 Has the individual been accused of obtaining a registration, license, provisional license or other authorization to operate as a cultivator, processor, or dispensary of medical marijuana in any jurisdiction by fraud, misrepresentation, or the submission of false information?

NO

B-3.19.1 If "**Yes**" to B-3.19, the reason for doing so must be provided below.

n/a

B-3.20 Has civil or administrative action been taken against the individual under the laws of Ohio or any other state, the United States or a military, territorial or tribal authority, relating to the individual's profession or occupation?

NO

B-3.20.1 If "**Yes**" to B-3.20, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.21 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees are a physician who has a certificate to recommend medical marijuana or who has applied for a certificate to recommend medical marijuana under section 4731.30 of the Revised Code.

YES

B-3.22 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees have ownership, investment interest, or a compensation arrangement with a laboratory licensed under Chapter 3796 of the Revised Code or an Applicant for a license to conduct laboratory testing.

YES

Compliance(Prospective Associated Key Employee Compliance)

Item 4 of 6

B-3.1 First Name

Alfonso

B-3.2 Middle Name

Thomas

B-3.3 Last Name

Traina

B-3.4 Proposed Role

PERSON WITH FINANCIAL INTEREST

B-3.5 Position/Title

Board Member

B-3.6 Brief description of role

Responsible for Corporate Strategy, Governance, Equity, Financing, Accounting

B-3.7 Has this individual served, or are they currently serving as an owner, officer, or board member of another medical marijuana entity in Ohio or the United States?

NO

B-3.7.1 If "**Yes**" to B-3.7, please provide the entity Name and Address.

n/a

B-3.8 Has this individual had ownership or financial interest, or do they currently have ownership or financial interest of another medical marijuana entity in Ohio or the United States?

NO

B-3.8.1 If "**Yes**" to B-3.8, please provide the entity Name and Address.

n/a

B-3.9 Has this individual ever been convicted of, or are charges pending for, a disqualifying offense? Include instances in which a court granted intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC, or TLC), or other diversion programs. Offenses must be reported regardless of whether the case has been sealed, as described in section 2953.32 of the Revised Code, or the equivalent thereof in another jurisdiction.

NO

B-3.9.1 If "**Yes**" to B-3.9, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.10 Has the individual ever been convicted of, or are charges pending for, any other felony offense under state or federal law?

NO

B-3.10.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.11 Has the individual ever been convicted of, or are charges pending for, a crime (felony or misdemeanor) involving an act of moral turpitude?

NO

B-3.11.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.12 Has this individual ever been disciplined by the State of Ohio Board of Pharmacy or any other licensing body.

NO

B-3.12.1 If "**Yes**", please provide the following: Name, Name and Address of Licensing Board, License Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved

n/a

B-3.13 Has the individual ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is such action pending?

NO

B-3.13.1 If "**Yes**" to B-3.13, the reason for doing so must be provided below.

n/a

B-3.14 Has the individual ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the surrender, suspension, revocation, or probation of the individual's license or registration?

NO

B-3.14.1 If "**Yes**" to B-3.14, the reason for doing so must be provided below.

n/a

B-3.15 Has the individual ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state jurisdiction that was based in whole or in part, on the Applicant's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

NO

B-3.15.1 If "**Yes**" to B-3.15, the reason for doing so must be provided below.

n/a

B-3.16 By selecting "**Yes**", this individual agrees to be enrolled in the Retained Applicant Fingerprint Database (Rapback) should the Applicant be awarded a provisional license.

YES

B-3.17 Has the individual been the subject of an action resulting in sanctions, disciplinary actions or civil monetary penalties being imposed relating to a registration, license, provisional license or any other authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.17.1 If "**Yes**" to B-3.17, the reason for doing so must be provided below.

n/a

B-3.18 Has the individual been the subject of a civil or administrative action relating to a registration, license, provisional license or authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.18.1 If "**Yes**" to B-3.18, the reason for doing so must be provided below.

n/a

B-3.19 Has the individual been accused of obtaining a registration, license, provisional license or other authorization to operate as a cultivator, processor, or dispensary of medical marijuana in any jurisdiction by fraud, misrepresentation, or the submission of false information?

NO

B-3.19.1 If "**Yes**" to B-3.19, the reason for doing so must be provided below.

n/a

B-3.20 Has civil or administrative action been taken against the individual under the laws of Ohio or any other state, the United States or a military, territorial or tribal authority, relating to the individual's profession or occupation?

NO

B-3.20.1 If "**Yes**" to B-3.20, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.21 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees are a physician who has a certificate to recommend medical marijuana or who has applied for a certificate to recommend medical marijuana under section 4731.30 of the Revised Code.

YES

B-3.22 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees have ownership, investment interest, or a compensation arrangement with a laboratory licensed under Chapter 3796 of the Revised Code or an Applicant for a license to conduct laboratory testing.

YES

Compliance(Prospective Associated Key Employee Compliance)

Item 5 of 6

B-3.1 First Name

Erica

B-3.2 Middle Name

Michelina

B-3.3 Last Name

Graves

B-3.4 Proposed Role

BOARD MEMBER

B-3.5 Position/Title

Board Member

B-3.6 Brief description of role

Legal, Corporate Strategy and Governance

B-3.7 Has this individual served, or are they currently serving as an owner, officer, or board member of another medical marijuana entity in Ohio or the United States?

YES

B-3.7.1 If "**Yes**" to B-3.7, please provide the entity Name and Address.

FFCP California Distribution & Processing/manufacturing facility
3911 West Capitol Ave.
West Sacramento, CA 95691

B-3.8 Has this individual had ownership or financial interest, or do they currently have ownership or financial interest of another medical marijuana entity in Ohio or the United States?

YES

B-3.8.1 If "**Yes**" to B-3.8, please provide the entity Name and Address.

FFCP California Distribution & Processing/Manufacturing facility
3911 West Capitol Ave.
West Sacramento, CA 95691

B-3.9 Has this individual ever been convicted of, or are charges pending for, a disqualifying offense? Include instances in which a court granted intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC, or TLC), or other diversion programs. Offenses must be reported regardless of whether the case has been sealed, as described in section 2953.32 of the Revised Code, or the

equivalent thereof in another jurisdiction.

NO

B-3.9.1 If "**Yes**" to B-3.9, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.10 Has the individual ever been convicted of, or are charges pending for, any other felony offense under state or federal law?

NO

B-3.10.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.11 Has the individual ever been convicted of, or are charges pending for, a crime (felony or misdemeanor) involving an act of moral turpitude?

NO

B-3.11.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.12 Has this individual ever been disciplined by the State of Ohio Board of Pharmacy or any other licensing body.

NO

B-3.12.1 If "**Yes**", please provide the following: Name, Name and Address of Licensing Board, License Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved

n/a

B-3.13 Has the individual ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is such action pending?

NO

B-3.13.1 If "**Yes**" to B-3.13, the reason for doing so must be provided below.

n/a

B-3.14 Has the individual ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the

surrender, suspension, revocation, or probation of the individual's license or registration?

NO

B-3.14.1 If "**Yes**" to B-3.14, the reason for doing so must be provided below.

n/a

B-3.15 Has the individual ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state jurisdiction that was based in whole or in part, on the Applicant's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

NO

B-3.15.1 If "**Yes**" to B-3.15, the reason for doing so must be provided below.

n/a

B-3.16 By selecting "**Yes**", this individual agrees to be enrolled in the Retained Applicant Fingerprint Database (Rapback) should the Applicant be awarded a provisional license.

YES

B-3.17 Has the individual been the subject of an action resulting in sanctions, disciplinary actions or civil monetary penalties being imposed relating to a registration, license, provisional license or any other authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.17.1 If "**Yes**" to B-3.17, the reason for doing so must be provided below.

n/a

B-3.18 Has the individual been the subject of a civil or administrative action relating to a registration, license, provisional license or authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.18.1 If "**Yes**" to B-3.18, the reason for doing so must be provided below.

n/a

B-3.19 Has the individual been accused of obtaining a registration, license, provisional license or other authorization to operate as a cultivator, processor, or dispensary of medical marijuana in any jurisdiction by fraud, misrepresentation, or the submission of false information?

NO

B-3.19.1 If "**Yes**" to B-3.19, the reason for doing so must be provided below.

n/a

B-3.20 Has civil or administrative action been taken against the individual under the laws of Ohio or any other state, the United States or a military, territorial or tribal authority, relating to the individual's profession or occupation?

NO

B-3.20.1 If "**Yes**" to B-3.20, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.21 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees are a physician who has a certificate to recommend medical marijuana or who has applied for a certificate to recommend medical marijuana under section 4731.30 of the Revised Code.

YES

B-3.22 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees have ownership, investment interest, or a compensation arrangement with a laboratory licensed under Chapter 3796 of the Revised Code or an Applicant for a license to conduct laboratory testing.

YES

Compliance(Prospective Associated Key Employee Compliance)

Item 6 of 6

B-3.1 First Name

Willis

B-3.2 Middle Name

Clark

B-3.3 Last Name

Triplett

B-3.4 Proposed Role

OTHER

B-3.5 Position/Title

Key Employee: Quality Improvement and Quality Assurance

B-3.6 Brief description of role

Oversees Quality Management Systems including Quality Assurance and Continuous Improvement, USP 797/800

B-3.7 Has this individual served, or are they currently serving as an owner, officer, or board member of another medical marijuana entity in Ohio or the United States?

NO

B-3.7.1 If "**Yes**" to B-3.7, please provide the entity Name and Address.

n/a

B-3.8 Has this individual had ownership or financial interest, or do they currently have ownership or financial interest of another medical marijuana entity in Ohio or the United States?

NO

B-3.8.1 If "**Yes**" to B-3.8, please provide the entity Name and Address.

n/a

B-3.9 Has this individual ever been convicted of, or are charges pending for, a disqualifying offense? Include instances in which a court granted intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC, or TLC), or other diversion programs. Offenses must be reported regardless of whether the case has been sealed, as described in section 2953.32 of the Revised Code, or the equivalent thereof in another jurisdiction.

NO

B-3.9.1 If "**Yes**" to B-3.9, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.10 Has the individual ever been convicted of, or are charges pending for, any other felony offense under state or federal law?

NO

B-3.10.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.11 Has the individual ever been convicted of, or are charges pending for, a crime (felony or misdemeanor) involving an act of moral turpitude?

NO

B-3.11.1 If "**Yes**", please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.12 Has this individual ever been disciplined by the State of Ohio Board of Pharmacy or any other licensing body.

NO

B-3.12.1 If "**Yes**", please provide the following: Name, Name and Address of Licensing Board, License Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved

n/a

B-3.13 Has the individual ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is such action pending?

NO

B-3.13.1 If "**Yes**" to B-3.13, the reason for doing so must be provided below.

n/a

B-3.14 Has the individual ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the surrender, suspension, revocation, or probation of the individual's license or registration?

NO

B-3.14.1 If "**Yes**" to B-3.14, the reason for doing so must be provided below.

n/a

B-3.15 Has the individual ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state jurisdiction that was based in whole or in part, on the Applicant's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

NO

B-3.15.1 If "**Yes**" to B-3.15, the reason for doing so must be provided below.

n/a

B-3.16 By selecting "**Yes**", this individual agrees to be enrolled in the Retained Applicant Fingerprint Database (Rapback) should the Applicant be awarded a provisional license.

YES

B-3.17 Has the individual been the subject of an action resulting in sanctions, disciplinary actions or civil monetary penalties being imposed relating to a registration, license, provisional license or any other authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.17.1 If "**Yes**" to B-3.17, the reason for doing so must be provided below.

n/a

B-3.18 Has the individual been the subject of a civil or administrative action relating to a registration, license, provisional license or authorization to cultivate, process, or dispense medical marijuana in any state?

NO

B-3.18.1 If "**Yes**" to B-3.18, the reason for doing so must be provided below.

n/a

B-3.19 Has the individual been accused of obtaining a registration, license, provisional license or other authorization to operate as a cultivator, processor, or dispensary of medical marijuana in any jurisdiction by fraud, misrepresentation, or the submission of false information?

NO

B-3.19.1 If "**Yes**" to B-3.19, the reason for doing so must be provided below.

n/a

B-3.20 Has civil or administrative action been taken against the individual under the laws of Ohio or any other state, the United States or a military, territorial or tribal authority, relating to the individual's profession or occupation?

NO

B-3.20.1 If "**Yes**" to B-3.20, please provide the following: Defendant, Name of Case and Docket Number, Nature of Charge or Complaint, Date of Charge or Complaint, Disposition, Name and Address of the Administrative Agency Involved, and Jurisdictional Court (Specify Federal, State and/or Local Jurisdictions)

n/a

B-3.21 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees are a physician who has a certificate to recommend medical marijuana or who has applied for a certificate to recommend medical marijuana under section 4731.30 of the Revised Code.

YES

B-3.22 By selecting "Yes", you attest to the following statement:
None of the Applicant's Prospective Associated Key Employees have ownership, investment interest, or a compensation arrangement with a laboratory licensed under Chapter 3796 of the Revised Code or an Applicant for a license to conduct laboratory testing.

YES

Business Plan(Property Title, Lease, or Option to Acquire Property Location)

C-1.1 Attach one of the following:

-Evidence of the Applicant's clear legal title to or option to purchase the proposed site and facility.

-A fully-executed copy of the Applicant's unexpired lease for the proposed site and facility and a written statement from the property owner that the Applicant may operate a medical marijuana organization on the proposed site for, at a minimum, the term of the initial provisional license.

-Other evidence that shows that the Applicant has a location to operate its medical marijuana organization.

Uploaded Document Name: **Lease 1561 Penn Ave combined doc.pdf**
NOTE: This applicant uploaded document is the next 2 page(s) of this document.

LEASE

MAGNUM INVESTMENTS, Inc., an Ohio corporation of East Palestine, Ohio, the lessor, leases to Ohio Valley Wellness LLC doing business as Ohio Valley Wellness LLC, the lessee, the premises situated in the City of East Liverpool, County of Columbiana, Ohio, known for street numbering purposes as 1561 Pennsylvania Ave.

1. TERM AND RENT. This lease shall be for the initial term of 10 years commencing on the date that the Lessee receives a license to dispense medical marijuana in the State of Ohio and this lease is contingent on the Lessee being granted a license to dispense medical marijuana in the State of Ohio. The rental rate shall be twenty-four thousand dollars ($24,000) per year, payable in equal monthly installments of two thousand dollars ($2,000.00) each on the first day of each month in advance. Lessee is hereby granted an option to renew said lease for an additional term agreed upon at that time and lessee has first right of refusal to purchase building.

2. COVENANTS of LESSEE. The lessee agrees to pay the rent, unless the premises are rendered untenable due to force majeure or intentional act by a third party or the lessor; to pay all water and sewer, and other utility bills charged or assessed during the term against the occupant of the premises excluding existing balances on utility bills prior to the commencement of the term; not to commit waste which would cause a decrease in the value of the premises; not to use the premises for any unlawful purposes according to the Laws of the State of Ohio; not to assign this lease, or sublet the premises, or permit the sale of his interest by legal process, without the written consent of the lessor; and at the expiration of this lease, to surrender the premises in as good condition as they are now, or may be put by the lessor, reasonable wear and unavoidable casualties expected. Lessee shall pay all required insurances and taxes promptly.

3. DEFAULT. Upon nonpayment of any of the rent for ten (10) days, after it becomes due, or upon the breach of any of the other agreements contained, or the lessee vacates the premises during the term of this lease, then the lessor may send notice to lessee to cure the potential breech. If after ten (10) days receipt of notice the issue has not been cured, the lessor may terminate this lease and reenter and repossess the premises without prejudice to the lessor's right of action for arrears of rent or breach of covenant.

4. *COVENANTS OF LESSOR. The lessor agrees (the lessee having performed all his* obligations under this lease) that the lessee shall occupy the premises during the term without any hindrance by the lessor, its successors or assigns, or any person lawfully claiming under him or them.

5. OTHER PROVISIONS.

A) All alterations or improvements required to make the premises suitable for lessee's intended use, shall be at Lessee cost and expense. Upon request, lessee shall provide to lessor, proof of payment of all improvements to the premises. Lessee shall be granted possession of the premises upon execution of this lease, for the purpose of making necessary alterations and improvements.

B) Lessee shall maintain adequate liability insurance, with lessor named as an additionally insured party on said policy.

Signed in our presence:

Jennifer J. Picha

Magnum Investments, Inc., Lessor

Print: Jennifer J. Picha 11/14/17

By: Timothy Figley

Print: _____

Title: PRESIDENT

The foregoing instrument was acknowledged before me this _____ day of 2017 by Timothy Figley, an Officer of Magnum Investments, Inc., who affirms that he is duly authorized to execute this instrument on behalf of said corporation.

Cynthia Figley
Witness

Joan Figley
Witness

_____

C-1.2 Business Name, as it appears on the Applicant's certificate of incorporation, charter, bylaws, partnership agreement or other official documents.

Ohio Valley Wellness, LLC

C-1.3 Trade names and DBA (doing business as) names

No response provided by applicant

C-1.4 Business Address

1561 Pennsylvania Ave. E.

C-1.5 City

East Liverpool

C-1.6 State

OH

C-1.7 Zip Code

43920

C-1.8 Phone

3302596969

C-1.9 Email

jpicha24@yahoo.com

Business Plan(Site and Facility Plan)

C-2.1 Applicants must show that they can expeditiously use a site and facility to meet the activities described in the provisional license by attaching one of the following:

- If the facility is in existence at the time that the provisional license application is submitted, submit plans and specifications drawn to scale for the interior of the facility.
- If the facility is in existence at the time that the provisional license application is submitted, and the Applicant plans to make alterations to the facility, submit renovation plans and specifications for the interior and exterior of the facility.
- If the facility does not exist at the time that the provisional license application is submitted, submit a plot plan that shows the proposed location of the facility and an architectural drawing of the facility, including a detailed drawing, to scale, of the interior of the facility.

Uploaded Document Name: **Ohio Valley Wellness Dispensary Floorplan (3).pdf**
NOTE: This applicant uploaded document is the next 1 page(s) of this document.

C-2.2 The Applicant also must submit evidence that it is in compliance with any local ordinances, rules, or regulations adopted by the locality in which the Applicant's property is located, which are in effect at the time of the application. Include copies of any required local registration, license or permit. If no relevant zoning restrictions have been enacted, provide a professionally prepared survey which demonstrates that the Applicant is not in violation of restrictions pertaining to prohibited facilities and is not located within 500 feet of a community addiction services provider as defined under section 5119.01 of the Revised Code. OAC 3796:5-5-01

Uploaded Document Name: **Notice of Proper Zoning Form.pdf**
NOTE: This applicant uploaded document is the next 2 page(s) of this document.

NOTICE OF PROPER ZONING FORM

(Attachment to Application Section C-2.2)

This form must be signed by an individual with authority to sign on behalf of the local government or zoning office where the Applicant proposes to locate its dispensary. The form must be printed and signed with an original, wet-ink signature. Electronic or digital signatures are not acceptable. Scan and attach a copy of the signed form, in PDF format, in response to Question C-2.2 of the online Application.

To be Completed by Applicant		
Business Name of Applicant: OHIO VALLEY WELLNESS, LLC. (Contact: Joe Piccin)		
Physical Address and Name of Proposed Medical Marijuana Dispensary: 1561 PENNSYLVANIA AVE. (OHIO VALLEY WELLNESS)		
City: EAST LIVERPOOL		County: COLUMBIANA
State: Ohio	Zip Code: 43920	Phone Number: (614) 659-9616

To be Completed by Zoning Authority or Local Government

Jurisdiction of Zoning Office or Local Government

City of East Liverpool

Moratorium (Required to check one box)

☑ The area of the City of East Liverpool HAS NOT enacted a local moratorium or taken other action that would prohibit the applicant from operating as a medical marijuana Dispensary.

☐ The area of _____ HAS enacted a local moratorium or taken other action that would prohibit the applicant from operating as a medical marijuana Dispensary. (Note: This will lead to disqualification of the application)

Zoning (Required to check one box)

☐ The area of _____ HAS NO zoning in place at this time.
*If Applicant checks this box, Applicant must also include a professionally prepared survey which demonstrates that the Applicant is not in violation of restrictions pertaining to prohibited facilities and is not located within 500 feet of a community addiction services provider as defined under section 5119.01 of the Revised Code.

☑ The area of the City of East Liverpool HAS zoning in place at this time and applicant's proposed facility appears to be planned in accordance with complying with all local zoning laws and regulations in place at the time of completion of this application.

Permit (Required to check one box)	
☐ The Applicant has received local zoning approval and was issued a permit. *If Applicant checks this box, Applicant must attach the permit issued. ☐ The Applicant has applied for local zoning approval, but was not yet issued a permit. ☑ No zoning approval was applied for and no permit was received at this time.	
Printed Name of Local Government Representative: William L. Cowan	Title: Director of Planning
Signature: William L Cowan	Date: Nov. 14, 2017

C-2.3 Provide a location map of the area surrounding the proposed facility that establishes the facility is at least 500 feet from a prohibited facility or a community addiction services provider as defined under section 5119.01 of the Revised Code. In establishing the distance between a proposed dispensary and such a facility, the distance shall be measured linearly and shall be the shortest distance between the closest point of the property lines of the proposed dispensary and the prohibited facility or community addiction services provider. The map must be clearly legible and labeled and may be divided into 8.5*11 inch sections. OAC 3796:5-5-01

Uploaded Document Name: **Proposed Dispensary to Closest Prohibited Property Line.PDF**
NOTE: This applicant uploaded document is the next 1 page(s) of this document.

565 FT

03/24/2014

Business Plan(Business Startup Plan)

C-3.1 A business startup plan is required for all dispensary provisional license applications. The business startup plan must provide a comprehensive set of activities necessary for the startup of the facility within six months of receiving a provisional license. Provide a timeline describing the process, methods, or steps used to execute a compliant business startup plan that includes, at a minimum:

1. Security and surveillance
2. Employee qualifications and training
3. Storage of medical marijuana products
4. Inventory management
5. Record-keeping
6. Prevention of medical marijuana diversion

This business entity was initialized in November 2017, with the goal of operating a professional, compassionate, educational and quality facility for the purposes of dispensing medicinal marijuana within our community. Ohio Valley Wellness LLC., is made up of a quality ownership group with vast medical and business experience, whom are wholly vested in this program and the opportunity to provide a much-needed service to the people of East Liverpool, and the county of Columbiana. The mission of Ohio Valley Wellness LLC., is to improve the health and wellness outcomes of our community by providing high-quality products and services that meet the unique needs of each patient and align with the standards of practice according to the Ohio Board of Pharmacy. It is our greatest passion to help patients obtain, or maintain their optimal overall health levels.

A Dispensary Forecast Model has been attached in Section C-3.1.1. This model will aid in providing a timeline for satisfying the requirement to have completed all startup criteria, and having Ohio Valley Wellness LLC dispensary within 6 months of receiving a provisional license. At the time the provisional license is issued, and within the first month, Ohio Valley Wellness LLC will begin securing and contracting bids on a proposed remodel of the facility and have architectural plans made of the tenant improvements for the facility. As a contractor is chosen, any permits, as required from the local jurisdiction, will be drawn, and materials ordered. During this first month, and continuous until opening, Associated Key Employees will begin to source available medical marijuana products from State licensed producers, to fulfill inventory needs for the dispensary. In month two, as we take possession of the building and begin the lease agreement, the remodel should begin, based on approved plans by the State and City.

By month three as the remodel is finished, telecommunications, informational technology, and security and surveillance infrastructure will be installed and operational. Inventory management software, as well as electronic record keeping data platforms will be installed. All systems will be tested to ensure they are in proper working order, and adhere to all criteria's applicable by Ohio Administrative Code pertaining to medical marijuana. In month three interviews, shall be conducted for qualified employees to fill the roles of Dispensary Key Employees, and Dispensary Support Employees. Entering month four, we will hire a Dispensary Key Employee to work alongside of the Associated Key Employee in completing the hiring of the remaining dispensary employee positions to be filled. At four and a half months, training for all dispensary employees shall begin on weekends to accommodate a four week training program, to include; security and surveillance, receiving of product, storage of product, dispensing of product, inventory management, diversion prevention, sanitation and safety, record keeping, security and infrastructure, patient care and education, software and applicable data platform training for operations and patient verification(if available at this time), and all applicable standard operating procedures for the business.

As we enter month 5, Ohio Valley Wellness LLC shall request the State Board of Pharmacy to conduct a final inspection to demonstrate the facility and all operations are ready upon approval to operate. Upon receiving the approval to operate from the State, all contracts shall be finalized with State Licensed suppliers of medical marijuana. In order to obtain an opening inventory for dispensary to

satisfy the associated patient and caregiver needs within, but not limited to, a 25 mile radius (will be an estimate). Before the end of the fifth month, OHIO VALLEY WELLNESS LLC WILL BE OPEN, and we look forward to serving and helping the community!

C-3.1.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in C-3.1. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final Ohio Valley Wellness Dispensary Model - FINAL for application December (2).pdf**
NOTE: This applicant uploaded document is the next 8 page(s) of this document.

Dispensary Forecast

			5 Months Out	4 Months Out	3 Months Out	2 Months Out	1 Month Out	Month 1
Revenue Days:								*20*
Patients/day:								*18*
Ave transaction $:								*$139*
Gross Revenue								**$50,169.03**
Wholesale Product Cost - Per Transaction								$79
Cost of Goods Sold								**$28,304**
Expenses								
Start-up								
	Ohio License Fee						$70,000	
	Facility Upgrades		$5,000	$65,000				
	Initial Inventory							$31,647
	Signage			$2,500				
	Energy Storage Battery (e.g., Tesla Powerwall)						$7,500	
	Security Setup				$15,000			
	Legal - Inc/ FOCUS Certification			$20,000				$20,000
Recurring Non-Labor Expenses								
	Facility Rental			$2,000	$2,000	$2,000	$2,000	$2,000
	Utilities							$1,500
	IT Costs			$500	$5,000	$500	$5,000	$500
	Discounts							$1,003
	Business Insurance			$500	$500	$500	$500	$1,000
	Office Furniture + Supplies				$8,000	$1,750	$1,500	$1,250
	Security 3rd Party (e.g., ADP)					$500	$500	$500
	Training			$2,000			$1,000	
	Janitorial							$800
	Energy Audits + Upgrades			$1,000				
	Marketing			$2,000	$1,000	$1,000	$0	$0
	Legal + Tax Preparation Fees					$2,000		
	Sales + Use Taxes							$3,637
Recurring Labor Expenses								
	Manager					$5,000	$5,000	$5,000
	Executive Management (no benefits)					$8,000	$6,000	$8,000
	Patient Specialist						$1,500	$3,000
	Patient Advocates						$1,500	$3,000
	Patient Instructor						$1,500	$3,000

	Security Guard						$0	$2,400
	Employer Taxes					$2,380	$2,838	$4,468
	Employee Benefits (30%)					$1,500	$2,850	$4,920
	Sub Total Expense		**$5,000**	**$95,500**	**$31,500**	**$25,130**	**$109,188**	**$97,625**
Total Expenses			**$5,000**	**$95,500**	**$31,500**	**$25,130**	**$109,188**	**$125,929**
EBITDA			**-$5,000**	**-$95,500**	**-$31,500**	**-$25,130**	**-$109,188**	**-$75,760**
Start Up Capital	**$345,000**							
Capital Reserve			**$340,000**	**$244,500**	**$213,000**	**$187,870**	**$78,682**	**$2,921**

Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
20	*20*	*20*	*20*	*20*	*20*	*20*	*20*	*20*	*20*	*20*
30	*36*	*50*	*55*	*66*	*79*	*95*	*114*	*116*	*119*	*121*
$139	*$174*	*$174*	*$174*	*$145*	*$174*	*$174*	*$174*	*$174*	*$174*	*$174*
$83,615.05	**$125,422.57**	**$174,198.01**	**$191,617.81**	**$191,617.81**	**$275,929.65**	**$331,115.58**	**$397,338.70**	**$405,285.47**	**$413,391.18**	**$421,659.01**
$79	$98	$98	$98	$82	$98	$98	$98	$98	$98	$98
$47,174	**$70,760**	**$98,278**	**$108,106**	**$108,106**	**$155,673**	**$186,807**	**$224,169**	**$228,652**	**$233,225**	**$237,889**
$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000
$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500
$500	$500	$500	$500	$500	$500	$500	$500	$500	$500	$500
$1,672	$2,508	$3,484	$3,832	$3,832	$5,519	$6,622	$7,947	$8,106	$8,268	$8,433
$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000
$1,000	$750	$750	$750	$750	$750	$750	$750	$750	$750	$750
$500	$500	$500	$500	$500	$500	$500	$500	$500	$500	$500
	$1,000			$1,000			$1,000			$1,000
$800	$800	$800	$800	$800	$800	$800	$800	$800	$800	$800
										$5,000
$0	$0	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000
				$2,000						$5,000
$6,062	$9,093	$12,629	$13,892	$13,892	$20,005	$24,006	$28,807	$29,383	$29,971	$30,570
				$1,000						$1,000
$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000
$6,000	$8,000	$6,000	$8,000	$6,000						
$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000
$3,000	$3,000	$3,000	$3,000	$3,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000
$3,000	$3,000	$3,000	$3,000	$3,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000

$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400
$4,101	$4,468	$4,101	$4,468	$4,101	$4,101	$4,101	$4,101	$4,101	$4,101	$4,101
$4,920	$4,920	$4,920	$4,920	$4,920	$6,720	$6,720	$6,720	$6,720	$6,720	$6,720
$46,456	**$53,439**	**$55,585**	**$59,562**	**$61,196**	**$66,795**	**$71,900**	**$79,025**	**$78,760**	**$79,510**	**$92,275**
$93,629	**$124,199**	**$153,863**	**$167,668**	**$169,302**	**$222,468**	**$258,707**	**$303,194**	**$307,412**	**$312,735**	**$330,164**
-$10,014	**$1,223**	**$20,335**	**$23,950**	**$22,316**	**$53,462**	**$72,409**	**$94,145**	**$97,873**	**$100,656**	**$91,495**
-$7,093	**-$5,870**	**$14,465**	**$38,415**	**$60,731**	**$114,193**	**$186,602**	**$280,747**	**$378,620**	**$479,276**	**$570,771**

Month 13	Month 14	Month 15	Month 16	Month 17	Month 18	Month 19	Month 20	Month 21	Month 22	Month 23
20	*20*	*20*	*20*	*20*	*20*	*20*	*20*	*20*	*20*	*20*
123	*126*	*128*	*131*	*134*	*136*	*139*	*142*	*145*	*148*	*150*
$163	*$163*	*$163*	*$163*	*$163*	*$163*	*$163*	*$163*	*$163*	*$163*	*$163*
$401,419.38	**$409,447.76**	**$417,636.72**	**$425,989.45**	**$434,509.24**	**$443,199.43**	**$452,063.41**	**$461,104.68**	**$470,326.78**	**$479,733.31**	**$489,327.98**
$92	$92	$92	$92	$92	$92	$92	$92	$92	$92	$92
$226,471	**$231,000**	**$235,620**	**$240,333**	**$245,139**	**$250,042**	**$255,043**	**$260,144**	**$265,347**	**$270,653**	**$276,067**
$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000	$2,000
$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500	$1,500
$500	$500	$500	$500	$500	$500	$500	$500	$500	$500	$500
$8,028	$8,189	$8,353	$8,520	$8,690	$8,864	$9,041	$9,222	$9,407	$9,595	$9,787
$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000
$750	$750	$750	$750	$750	$750	$750	$750	$750	$750	$750
$500	$500	$500	$500	$500	$500	$500	$500	$500	$500	$500
		$1,000			$1,000			$1,000		
$800	$800	$800	$800	$800	$800	$800	$800	$800	$800	$800
$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000	$1,000
					$2,000					
$29,103	$29,685	$30,279	$30,884	$31,502	$32,132	$32,775	$33,430	$34,099	$34,781	$35,476
					$1,000					
$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000	$5,000
$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000
$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000
$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000

$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400	$2,400
$4,101	$4,101	$4,101	$4,101	$4,101	$4,101	$4,101	$4,101	$4,101	$4,101	$4,101
$6,720	$6,720	$6,720	$6,720	$6,720	$6,720	$6,720	$6,720	$6,720	$6,720	$6,720
$78,403	**$79,145**	**$80,903**	**$80,675**	**$81,464**	**$86,267**	**$83,087**	**$83,924**	**$85,777**	**$85,647**	**$86,534**
$304,873	**$310,146**	**$316,523**	**$321,008**	**$326,603**	**$336,309**	**$338,130**	**$344,067**	**$351,123**	**$356,300**	**$362,601**
$96,546	**$99,302**	**$101,114**	**$104,981**	**$107,906**	**$106,890**	**$113,933**	**$117,037**	**$119,204**	**$123,433**	**$126,727**
$667,317	**$766,619**	**$867,733**	**$972,714**	**$1,080,620**	**$1,187,511**	**$1,301,444**	**$1,418,481**	**$1,537,685**	**$1,661,118**	**$1,787,845**

Month 24	Period Results
20	
153	
$163	
$499,114.54	**$8,445,232.57**
$92	
$281,588	**$4,764,588.19**
	$0
	$0
	$70,000
	$70,000
	$31,647
	$7,500
	$15,000
	$40,000
$2,000	$56,000
$1,500	$36,000
$500	$23,000
$9,982	$168,905
$1,000	$26,000
$750	$30,000
$500	$13,000
$1,000	$11,000
$800	$19,200
$5,000	
$1,000	$25,000
$5,000	$16,000
$36,186	$612,279
$1,000	$4,000
$5,000	$130,000
$3,000	$73,500
$6,000	$127,500
$6,000	$127,500

$2,400	$57,600
$4,101	$104,752
$6,720	$154,830
$99,440	**$2,119,712**
$381,027	**$6,884,301**
$118,087	**$1,560,932**
$1,905,932	

C-3.2 The Business Startup Plan also must describe how the Applicant's proposed business operations will comply with statutory and regulatory requirements (as described in Chapter 3796 of the Revised Code and division 3796:6 of the Administrative Code) necessary for the startup and continued operation of the facility including, but not limited to:

1. Security and surveillance
2. Employee qualifications and training
3. Storage of medical marijuana products
4. Inventory management
5. Record-keeping
6. Prevention of medical marijuana diversion

Ohio Valley Wellness has contracted with Foundation of Cannabis Unified Standards for certification and ongoing compliance assistance. Founded in 2014 as The Cannabis Health and Safety Organization, FOCUS addresses the many short comings in quality, safety, and consistency that became evident with the explosive growth of the global legal cannabis industry. FOCUS is an international, non-profit, cannabis standards development & third-party certification organization dedicated to protecting public health, consumer safety and safeguarding the environment.

The FOCUS certification process is designed to simplify compliance using powerful digital tools and proven processes for quality and safety. Under FOCUS certification, a business receives ongoing advisory services, SOPs, comprehensive employee training and a documentation management software system to track and prove compliance. costs and reducing liability.

By working with FOCUS, Ohio Valley Wellness has taken a proactive approach to cannabis quality management through the implementation of industry wide, cannabis specific, Good Manufacturing Practice standards and third-party certification. FOCUS provides a digital document management and compliance system, PowerDMS, that will track and assure Ohio Valley Wellness' maintains compliance with all statutory and regulatory requirements, as well as FOCUS standards. Semiannually, FOCUS conducts both a digital and onsite assessment of Ohio Valley Wellness business operations to assure they are meeting all statutory and regulatory requirements.

PowerDMS will house and maintain all process, procedures, logs, and other operational records for Ohio Valley Wellness. This allows access to the most up to date records and documentation at all times, while providing a simple traceability system to track any changes, when they were made and by who.

1. Security and Surveillance - To satisfy OAC 3796:6-3-16 Monitoring, surveillance, and security requirements.
Ohio Valley Wellness will create and implement a detailed security and surveillance plan that meets all Ohio statutory and regulatory requirements, as well as all items in the FOCUS Dispensary Standard, including:

• Security qualifications, roles and responsibilities
• Physical Security – access, alarms and video surveillance
• Confidentiality and Information Security
• Security Training
• Security Incident Reporting
• Background Checks
• Security Risk Assessments
• Transport security

• Security of Records
• Facility access – worker ingress and egress
• Emergency policies and procedures

2. Employee Qualifications and Training – To satisfy OAC 3796:6-3-19 Employee training requirements.
Ohio Valley Wellness will utilize FOCUS training through the PowerDMS platform, as well as other resources that meet all Ohio statutory and regulatory requirements to assure employees are maintaining compliance with:
• Applicable Laws and Regulations
• Company Policies and Procedures
• Cash Management
• Patient Care

3. Storage of Medical Marijuana – To satisfy OAC 3796:6-3-07 Security, control, and storage of medical marijuana at a dispensary
Ohio Valley Wellness will utilize FOCUS Dispensary Standard through the PowerDMS platform to assure the storage of medical marijuana meets or exceeds all statutory and regulatory requirements, including but not limited to:
• Product Storage
• Storage Area Access Control
• Quarantined Material Segregation
• Storage Area Construction
• Cleaning
• Pest Control
• Hazardous Materials
• Cross Contamination Prevention

4. Inventory Management - To satisfy OAC 3796:6-3-20 Medical marijuana dispensary internal inventory control system, and OAC 3796:6-3-21 Recall procedures.
Ohio Valley Wellness will utilize FOCUS Dispensary Standard through the PowerDMS as well as a Seed to Sale Tracking System and the state platform to assure Inventory Management meets or exceeds all statutory and regulatory requirements, including but not limited to:
• Traceability and Withdrawal System
• Product Recall Program
• Recall Mock Test
• Complaints Procedures

5. Record Keeping – To satisfy OAC 3796:6-3-17 Record keeping requirements.
Ohio Valley Wellness will maintain a Records Management System that meets all requirements as laid out in Ohio Administrative Cord 3796:6-3-17 for the storage and retrieval of patient information and other medical marijuana records. Ohio Valley Wellness will establish procedures to ensure the organized storage, retention and protection of all records and supporting data through the FOCUS/PowerDMS software system and will include, but is not limited to:
• Confidentiality
• Accessibility by the state board of pharmacy
• Safeguards against erasures & unauthorized changes
• Contains a true audit trail
• Capable of being reconstructed or retrieved
• Records all medical marijuana received, dispensed, sold, destroyed or used
• Records are backed up daily

Documentation maintained in the normal course of business will include, but are not limited to:
• Background checks
• Operating Procedures
• Inventory Records
• Audit Reports
• Staffing Plan
• Business records including:
o Assets and Liabilities
o Third-party Vendor List
o Monetary Transactions
o Bank Statements, journals, legers, agreements, checks, invoices, vouchers, surveillance records, attendance logs, employee training records, quality assurance review logs

• Records Inventory List, including control requirements
• Retention Time
• Destruction/Deletion methods, schedules and processes
• HIPPA Compliance
• Data Encryption
• Data Backup
• Automatic File Backup
• Lockable Filing System
• Long-term storage/environmental controls
• Records Assessment every 90 days

6. Prevention of Medical Marijuana Diversion
Ohio Valley Wellness will take every possible precaution to prevent the diversion and theft of medical marijuana. In addition to meeting all statutory and regulatory requirements, we will also adhere to FOCUS Dispensary Standard's Theft and Diversion requirements, including but not limited to:
• Supplier Qualifications
• Employee qualifications
• Use of physical security measures in facility
• Additional security devices on "high risk" products (RFID Sticker)

Business Plan(Description of Employee Duties and Roles)

C-4.1 Please provide a description of the duties, responsibilities, and roles of each Prospective Associated Key Employee. Please attach a Table of Organization and Control for the business. Include all individuals listed in question A-6.

Ohio Valley Wellness, LLC will retain two key employees responsible for overseeing on-site operations. Those individuals are the President and Chairman of the Board, Jennifer Picha Pharm D., and Victor Garman, Vice President of Operations and Member of the Board of Directors. In maintaining their obligation and responsibility to the company for regulatory compliance these individuals have assumed the following duties:

Jennifer Picha Pharm D.
• Daily - Onsite Operations Director
• Employee Qualifications and Training Director
• Inventory management Director
• Security and Surveillance Director
• Diversion Prevention and Response Director
• In the event a recall is necessary will perform the roles of product recall coordinator and spokesperson
• Chairman of the Board

Victor Garman
• IT support
• Oversight of digital systems pertinent to:
o Inventory Management,
o Security and Surveillance
o Record Keeping.
• In the event of a recall willl be responsible for retrieving quantities, and date codes of all products shipped or sold from the inventory control system
• Board Member
Joseph Pappas
• Serve as Chief Financial Officer
• Oversee equity financing
• Communicate with CPA for accounting services
• Corporate Strategy and Governance
• Board Member
Alfonso Traina
• Equity Financing
• Corporate Strategy and Governance
• Board Member
Erica Graves-Picha
• Corporate Strategy and Governance
• Board Member
Willis Triplett
• Quality Assurance Consultant
• Continuous Improvement

C-4.2 Please attach a Table of Organization and Control for the business. Include all individuals listed in question A-6.

Uploaded Document Name: **Associated Key Employee Roles and Responsibilities (2).pdf**

NOTE: This applicant uploaded document is the next 1 page(s) of this document.

Key Employee	Title	Short description of role / responsibilities:
Jennifer Picha	President, Chairman of Board	Associated Key Employee Responsible for daily onsite operations during business hours as well as Employee Qualifications and Training; Inventory management including inspection during receiving operations and daily inventory audits; Security and Surveillance; Diversion Prevention and Response. In the event a recall is necessary will perform the roles of product recall coordinator and spokes person.
Victor Garman	Vice President of Operations, Board Member	Associated Key Employee Responsible for maintaining IT support and oversight of digital systems pertaining to Inventory Management, Security and Surveillance and Record Keeping. In the event of a recall will be responsible for retrieving quantities, and date codes of all products shipped or sold from the inventory control system
Joseph Pappas	CFO, Board Member	Associated Key Employee Responsible for Equity financing, corporate strategy and governance
Alfonso Traina	Board Member	Associated Key Employee Responsible for Equity financing, corporate strategy and governance
Erica Graves	Board Member	Associated Key Employee Responsible for Legal, corporate strategy and governance
Willis Triplett	Key Employee	Key Employee Responsible for Quality Assurance, Continuous Improvement, USP 797/800

Business Plan(Capital Requirements)

Item 1 of 1

C-5.1 Type of Capital

Liquid

C-5.2 Source of Capital

Jennifer Picha

C-5.3 Name and Address of financial institution

This response has been entirely redacted

C-5.4 Account Number

This response has been entirely redacted

C-5.5 Illustrate that the Applicant has adequate liquid assets to cover all expenses and costs for the first year of operation as indicated in the dispensary's proposed Business Startup Plan (Question C-3). The total amount of liquid assets must be no less than $250,000. Provide **unredacted** documentation from the Applicant's financial institution to support these capital requirements. (ORC 3796:6-2-02)

This response has been entirely redacted

C-5.5.1 Please attach a **redacted** copy of documentation from the Applicant's financial institution to support the capital requirements. (ORC 3796:6-2-02)

Uploaded Document Name: **Redacted Notarized Letter of Liquid Assests.pdf**
NOTE: This applicant uploaded document is the next 1 page(s) of this document.

PNC BANK

11/13/2017

Jennifer Picha
2632 Hidden Canyon Drive
Brecksville, OH 44141

Dear To whom it may concern,

In response to your request that PNC Bank, National Association provide written verification concerning your (checking/savings/certificate of deposit) account(s), we are providing the following information:

Account No.	Date Opened	Balance as of date of this letter
[redacted]	06/16/1998	$235,797.12

This information is subject to any outstanding items or charges.

Sincerely,

PNC Bank, National Association

Molly McClurg
Assistant Branch Manager

CUSTOMER AUTHORIZATION/ ACKNOWLEDGEMENT

I/we hereby acknowledge that I/we have requested and authorized PNC Bank, National Association to provide this written verification concerning my/our (checking/savings/certificate of deposit) account(s).

Dated this 13 day of Nov, 2017.

Customer Signature: _____

Customer Signature: _____

Molly McClurg, Notary Public

MOLLY MCCLURG, NOTARY PUBLIC

BDMS0007-0617

Business Plan(Business History and Experience)

Item 1 of 3

C-6.1 First Name

Jennifer

C-6.2 Middle Name

Janell

C-6.3 Last Name

Picha

C-6.4 Previous Role (e.g. Owner, Officer, Board Member, Person with Financial Interest, Person Exercising Substantial Control, Support Employee)

Support Employee - Pharmacy Manager, Pharmacy Director, General Manager

C-6.5 Business Name

Curascript Infusion Pharmacy/Walgreens Infusion Pharmacy/OptionCare

C-6.6 Business Address

Dayton, Ohio

C-6.7 Position of management or ownership of a controlling interest

YES

C-6.8 Dates

June 2006 - Feb 2011

Business Plan(Business History and Experience)

Item 2 of 3

C-6.1 First Name

Victor

C-6.2 Middle Name

James

C-6.3 Last Name

Garman

C-6.4 Previous Role (e.g. Owner, Officer, Board Member, Person with Financial Interest, Person Exercising Substantial Control, Support Employee)

Director of Project Management

C-6.5 Business Name

Trimark Associates, Sunverge, Alstom Grid, NV Energy

C-6.6 Business Address

2365 Iron Point Rd #100, Folsom, CA 95630

C-6.7 Position of management or ownership of a controlling interest

YES

C-6.8 Dates

November 2009 - Present

Business Plan(Business History and Experience)

Item 3 of 3

C-6.1 First Name

Joseph

C-6.2 Middle Name

Clark

C-6.3 Last Name

Pappas

C-6.4 Previous Role (e.g. Owner, Officer, Board Member, Person with Financial Interest, Person Exercising Substantial Control, Support Employee)

Owner

C-6.5 Business Name

Jay Pappas, LLC.

C-6.6 Business Address

3197 Forest Hills Dr. East Liverpool, OH 43920

C-6.7 Position of management or ownership of a controlling interest

YES

C-6.8 Dates

2013 - Present

Business Plan(Business History and Experience Narrative)

C-6.9 Provide a narrative description not to exceed 1500 words demonstrating any previous experience at operating other businesses or non-profit organizations and any demonstrated knowledge or expertise with regard to the medical use of marijuana to treat qualifying conditions (for all Prospective Associated Key Employees with an ownership interest of ten percent or more in the prospective dispensary). Include the number of years of experience, the type of business, and any administrative discipline history associated with each business.

Jennifer Picha, PharmD - Narrative
I've always had the passion and drive to learn new things, which led me to the evolving field of pharmacy, and specifically Home Infusion. It's multifaceted and the pharmacists get to dive into pharmacy, dabble in business and help lead a team through continuity of care. During my 5 years as a manager in Home Infusion (with no administrative discipline history), I was asked to forecast our patient population weekly as it related to revenue. I was floored by the increasing use of pain pumps and modulators for our patients. This led me to search for other solutions for these very sick patients on opioids and other pain medications, causing a multitude of side effects along with other negative effects. At that point, I came across the rapidly growing field of medical marijuana and scientific effects on the brain and other systems throughout the body. Naturally, I was intrigued by the potential role medical marijuana could play in our very sick population. The Institute of Medicine published a report in 1999 entitled, "Marijuana in Medicine." This was a start to a new world filled with cannabinoids, pain receptors, pharmacokinetics and pharmacodynamics of an old compound but a better understanding of marijuana's properties. In this report, they found that different cannabinoid receptor types play various roles in the body including pain modulation, control of movement and memory. Since that initial science-based study, there have been multiple journal articles observing the specifics of cannabinoid pharmacokinetic and pharmacodynamic properties that make the compounds unique. Medical marijuana has many benefits that will continue to be explored and substantiated as we head down this path of enhancing our knowledge for the betterment of our patients.

Victor Garman - Narrative
I have 22 years of professional experience as a business owner, management, and technology consultant, and program manager. As a certified project management professional and certified energy manager, I have successfully led dozens of projects to deliver services and products to companies both in the U.S. and abroad. Over more than two decades, I have managed many budgets ranging in size from the low thousands to the tens of millions of dollars. I have supervised branch offices for large, international corporations. I have also managed a retail store. Currently, I am managing a team of project managers, and am responsible for the profitability of well over ten million dollars in company projects.

When I moved to California, I became a medical marijuana patient. As a medical marijuana patient, I utilized medical marijuana, as prescribed by my doctor, to treat chronic medical conditions. As such, I have first-hand knowledge of medical marijuana as a patient and customer of marijuana dispensaries in California.

I have never had administrative discipline with any employer.

Jay Pappas - Narrative
I've always had a passion for business, and in February 2013, I had the opportunity to turn my passion into reality. In the last 4 years, I have successfully grown the business to over $3,000,000 in annual sales and more than 20 employees. The success of the company is directly related to how I have built relationships with various drilling companies as well as vendors and employees. I believe that making

and maintaining relationships is extremely important in all businesses and will continue that trend into the medical marijuana business.

I am a local resident of East Liverpool where the medical marijuana dispensary will be located. I have many supportive contacts of the medical marijuana dispensary including the mayor, safety service director, and city planner. The city planner has gone so far as to write a letter of recommendation in support of Ohio Valley Wellness LLC., which is included below in this narrative as well as attached at D-10.1.1. Economic development and growth will be profound in our city, who supports this business entity. The dispensary has the potential to add important benefits to our community including health options , revenue, and employment opportunities all for the betterment of our community.

I have never had administrative discipline with any employer.

East Liverpool, OH has median household income of less than $30,000, and the poverty rate is 28.9% (2011-2015 data). The presence of a medical marijuana dispensary in this community will not only bring healthcare services and jobs to a rural, economically impoverished part of our state, but it will also provide myself and my colleagues with the opportunity to embrace and live our passions.

City of East Liverpool Department of Planning and Development (See attachment at D-10.1.1)

November 14, 2017

To whom it may concern,
I believe that establishing a medical marijuana dispensary in our community would
expand options for patients in our community and across the state to utilize medical marijuana for management of medical afflictions as an alternative to more dangerous addictive prescription medications.
As a proponent of medical marijuana as an option for our community members, I support this application to establish a medical marijuana dispensary license to Ohio Valley Wellness LLC. The dispensary has the potential to add important benefits to our community including
health options, revenue to our city, and employment opportunities all for the betterment of our community.
I highly recommend this business, Ohio Valley Wellness LLC, and support this endeavor to help lead the community to more aligned wellness.
Director of Planning
Bill Cowan

Operations Plan(Dispensary Oversight)

D-1.1 By selecting "Yes", the Applicant attests that it will appoint a designated representative responsible for the oversight, supervision and control of operations of the medical marijuana dispensary. When there is a change in the appointed designated representative, the Applicant will notify the State Board of Pharmacy within 10 business days of appointment. OAC 3796:6-3-05

YES

Operations Plan(Security and Surveillance)

D-2.1 By checking “Yes,” the Applicant attests that it is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding medical marijuana and medical marijuana products.

YES

D-2.2 Please provide a summary of the Applicant's proposed security and surveillance equipment and measures that will be in place at the proposed facility and site. These measures should cover, but are not limited to, the following:

1. General overview of the equipment, measures and procedures to be used
2. Alarm systems
3. Surveillance system
4. Surveillance storage
5. Recording capability
6. Records retention
7. Premises accessibility
8. Inspection/servicing/alteration protocols

Please reference OAC 3796:6-3-16 for more information.

This response has been entirely redacted

D-2.2.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-2.2. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final D-2.2.1 Images, Safety Checklist, Security SOP.pdf**
NOTE: This applicant uploaded document is the next 18 page(s) of this document.

1.0 SCOPE

1.1. Procedures for the security of people, products, information, vehicles, facilities and operations involved in the production of cannabis and cannabis products.

2.0 OBJECTIVES

2.1. Define the responsibilities, requirements and processes to implement and maintain an effective security program that protects all assets, people, products, equipment, structures and operational processes from risks and threats.

2.2. Ensure all workers, contractors, suppliers, inspectors, government agents and visitors follow all security procedures.

3.0 RESPONSIBILITIES

3.1. Management rigorously protects the people, products, information, systems and assets associated with business operations from risks and threats.

3.2. Management stays current with evolving security risks, conducts periodic risk assessments and makes appropriate improvements to the security program.

3.3. Management ensures all workers receive ongoing security training and follow security procedures.

3.4. Managers and supervisors implement and sustain security procedures and constantly observe behaviors and report any potential risk to the Security Manager.

3.5. Workers understand and follow all security procedures and report any risks or suspected violations to their manager or the Security Manager.

4.0 DEFINITIONS AND ABBREVIATIONS

4.1. Risk/Threat – Any potential area where people, products, assets, operations, information, customers or any other element of the business is vulnerable to unauthorized or illegal activity.

4.2. Security Incident – Security breaches, attempted/actual crimes, disappearance of products or materials, lack of procedural diligence, workplace violence or threats by workers, customers, suppliers or others, or suspicious activity that warrants investigation.

4.3. Security Manager – Person with the authority, skills and experience responsible for developing, implementing and sustaining a secure business operation as defined in the operation's Security Plan.

4.4. Security Plan – The plan that identifies the structure, processes, responsibilities and systems required to ensure secure, legal operations.

5.0 PROCEDURE

5.1. Security Plan

5.1.1. The operation develops and maintains a comprehensive Security Plan that protects the business assets, facilities, products, workers, visitors and the community from risks and threats.

5.1.2. The Security Plan includes:

a. Company security mission and purpose

b. Security roles and responsibilities

c. Confidentiality and information security

d. Security systems – access, alarms and video surveillance

e. Cash management

f. Record keeping and reporting

g. Employee policies and disciplinary action

h. Dynamic entry, intrusion, theft, loss and diversion

i. Facility access, worker ingress/egress

j. Inventory control – seed to sale

k. Safety policy

l. Emergency policies and procedures

5.1.3. The operation contracts professional security personnel to develop, implement and review the security plan.

5.1.3.1. The operation qualifies and manages security suppliers as required by SOP-MAT-01 Supplier Qualification and applicable purchasing procedures.

5.1.4. The operation establishes communication with local law enforcement to gather input for the Security Plan and build support for security and emergency plans and procedures.

5.1.5. The operation designs crime prevention mechanisms and methods into the physical and operational environment using Crime Prevention Through

Environmental Design (CPTED) or similar security methodology. Methods include:

5.1.5.1. Natural access controls

5.1.5.2. Target hardening

5.1.5.3. Image management

5.1.5.4. Security-based maintenance

5.1.5.5. Formal surveillance

5.1.5.6. Activity support (resident/neighbor engagement)

5.1.5.7. Local law enforcement collaboration

5.2. Security Risk Assessment

5.2.1. The Security Manager facilitates an initial and annual Security Risk Assessment that reviews all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials and information).

5.2.2. The Risk assessment documents all risks, mitigation plans and responsibility for management and corrective action. Risks include:

a. Exteriors/perimeter

b. Doors, windows and other openings

c. Interior areas of site or building

d. Property and equipment

e. General security processes/protocol

f. Alarm systems

g. Security employees and contractors

h. Cash management procedures

i. Worker procedures

j. Worker and background checks

k. Opening and closing the facility

l. Managing and removing trash

m. Working with vendors

n. Working with contractors

o. Threats from neighbors

p. Training and monitoring employees

q. General management practices

r. Managing security emergencies

s. Plans for dynamic entry or intentional threats

5.3. Security Staff Qualifications

5.3.1. The operation has established qualifications and procedures for onsite security personnel and ensures all security personnel are trained in and follow company and security policies and procedures.

5.3.1.1. Security managers have documented security training and demonstrated security experience that qualifies them to competently oversee all security responsibilities.

5.3.1.2. Security officers are trained in security procedures and company polices on cannabis security at the facility.

5.4. Security Training for Workers

5.4.1. The operation provides and documents security training for all workers including training on:

a. Dynamic entry

b. Alarm system operations

c. Emergency and evacuation procedures

d. Crisis management

e. Law enforcement interaction

f. Other topics vital to worker, customer, supplier and facility security

5.4.2. The operation designates a qualified security trainer to provide security training to all workers; evidence of qualifications includes documented security training or verified security experience.

5.4.3. The security manager observes and interviews all workers monthly to ensure they understand and follow company security policies and procedures.

5.5. Security of Records and Information

5.6. All electronic records are stored in a system that is secure, password-protected and limits data access to those who need it.

5.6.1. Data is encrypted when feasible.

5.6.2. The operation maintains a secure offsite backup/storage system.

5.6.3. All hard copy files and records are controlled by limiting access to file storage areas, locking filing systems when not in use and requiring sign-out logs when records are removed for review.

5.6.4. Security Manager maintains a list of personnel authorized to access security records.

5.6.5. Security Manager controls records using a sign in/sign out log; supervises and facilitates records/video reviews with authorized personnel if necessary to control records or information.

5.7. Security Incident Reporting

5.7.1. The Security Manager documents each security incident in a Security Incident Report that records all relevant facts:

a. Date of incident

b. Description of incident

c. Criminal or civil charges filed or pending

1. Situation
2. Sequence of events
3. Injuries
4. Losses
5. Violations
6. Law enforcement involvement

d. Eminent threats and critical/Immediate responses required

e. People involved including government agencies

f. Security investigator

g. Investigation results

h. Corrective actions – processes, procedures, systems, people

i. Discipline recommendations

5.7.2. The investigating manager ensures all information is complete and detailed on the incident report to facilitate effective problem solving and corrective action.

5.7.3. Reports are initiated immediately, followed up on consistently and closed as promptly as possible.

5.8. Background Checks

5.8.1. The operation completes a criminal background check on all workers, including management and contract workers, using a bonded, certified or authorized service.

5.8.1.1. Workers pre-authorize the background check in writing or using e-signature.

5.8.1.2. Background reports are kept confidential except as required for procedural decisions.

5.8.1.3. Reports are stored in a secure filing system or computer records management system and are retained for two years after worker termination.

5.8.2. The operation establishes criteria for hiring/not hiring before conducting a background check.

5.8.3. The hiring manager documents all rejections based on background check reports.

5.8.3.1. Hiring criteria is defined in job description, interview plan and company policies.

5.8.4. Criminal background checks review at least five years' history for felony convictions in all U.S. states and territories; the operation conducts international reports as required depending on candidates and location.

5.8.5. Theft, embezzlement or felony drug convictions should prevent employment; all employment restrictions should be clearly documented on the operation's pre-employment information.

5.8.6. Workers are required to notify their manager if they are convicted of a felony, receive any drug-related conviction or experience an occurrence known to be a violation of the worker policy manual at any time during their employment or work contract.

5.8.7. Background checks comply with federal, state and local employment and privacy laws.

5.9. Physical Security

5.9.1. Physical Barriers

5.9.1.1. The operation applies methods to prevent unauthorized access to buildings, production areas and products, shipping/receiving, storage and parking areas.

5.9.1.2. Prevention methods include fencing, locked gates, secure doors, window protection, automatic access systems and other physical barriers and reinforcements.

5.9.1.3. Security barriers comply with local security, fire safety and zoning regulations and GMP.

5.9.2. Grounds and External Areas

5.9.2.1. The security plan ensures external areas are clear of obstructions, well illuminated and covered by surveillance systems.

5.9.2.2. Includes adjacent buildings, neighboring businesses and residential areas, ingress and egress and exterior signage.

5.9.2.3. Workers are trained on safe ingress/egress processes.

5.9.3. Door Locks

5.9.3.1. Sturdy commercial-grade locks are installed on all doors and gates.

5.9.3.2. External doors have deadbolt locks and comply with local fire and building code regulations.

5.9.3.3. Key distribution is controlled, monitored and documented.

a. Security Manager maintains key control process including key log and physical key control.

5.9.3.4. RFID access cards are controlled and monitored; RFID key cards are used in conjunction with a PIN code.

5.9.3.5. When used, biometric entry systems are monitored, controlled, serviced and documented.

5.9.3.6. Procedures ensure keys, locks, codes and biometrics are changed immediately as required by personnel access privilege changes or breaches.

a. Manager immediately notifies security manager when a worker is terminated for any reason.

b. Manager provides advance notification to Security Manager when appropriate for any at-risk terminations or when workers are under investigation.

5.9.3.7. Keypad locks (used solo without key card or biometrics) are not permitted for restricted areas or external entry.

5.9.4. Facility Access Controls: The operation has documented procedures to control access to the operation's facilities.

5.9.4.1. Procedures detail access for workers, contractors, managers and visitors including customers, inspectors, law enforcement and regulators.

a. Workers wear visible identification badges.

b. Process is in place to remove access for terminated workers.

c. At least weekly, the security manager or designee reviews entrance access logs to prevent unauthorized access after-hours or off shift.

5.9.4.2. Restricted Area Access Controls

a. The operation controls access to restricted areas including areas containing controlled products, safety hazards, contamination risks or sensitive information.

b. Signs clearly identify restricted areas

c. The Security Manager sets and maintains parameters for authorized access and document the physical controls implemented.

1. Access to production areas is limited to production staff and authorized, escorted visitors.

2. The Security Manager maintains a master access list that lists each restricted area and the person/position authorized to enter.

3. The Security Manager ensures RFID cards, codes, keys and other access credentials are recorded in the Key Log.

4. Access to storage areas is limited to the workers on the authorized Storage Access List.

5.9.4.3. Active controls such as locks, keypads, barriers and/or security personnel are in use to restrict access.

5.9.4.4. Restricted areas have logs or digital records to indicate time, date and person accessing the area.

5.9.4.5. Restricted areas have appropriate inventory controls and documentation for products and materials.

5.9.4.6. Restricted areas are marked with signage indicating "Restricted Area – Authorized Personnel Only."

5.9.4.7. Procedures cover access by visitors, contractors, suppliers, regulatory and law enforcement officials.

5.9.4.8. Managers monitor restricted area access reports on a periodic basis.

5.9.5. Visitor Access Controls

5.9.5.1. An authorized worker ensures all visitors sign in and out of the facility (name, organization, purpose of visit, date, time and escort) in a visitor log.

5.9.5.2. All visitors are escorted by an authorized person at all times while in controlled areas of the facility.

5.9.5.3. Visitors wear a visible identification badge while on the premises.

5.9.5.4. Visitor log is retained for two years.

5.9.6. Product Control

5.9.6.1. All areas where cannabis or cannabis-derived products are processed or stored are controlled, locked and access restricted to authorized personnel.

5.9.6.2. Current inventory records are maintained for work-in-process and finished goods.

5.9.6.3. A commercial vault is installed as required by the Security Risk Assessment and Security Plan.

5.9.6.4. Signs that read "Restricted Area – Authorized Personnel Only" or equivalent are posted in all areas where cannabis or cannabis products are processed and stored.

5.9.7. Theft/Product Loss Plan

5.9.7.1. The operation has emergency procedures for securing all product and currency following any instance of diversion, theft or loss of cannabis.

5.9.7.2. The facility manager and/or security manager conduct a Security Risk Assessment to determine whether additional safeguards are required; they update procedures and implement changes to training as required.

5.9.8. Cash Management

5.9.8.1. The operation provides documented cash management training to workers who handle cash, including managing cash transactions with customers and suppliers.

5.10. Alarm Systems

5.10.1. The operation is continuously monitored by a building-wide alarm system.

5.10.1.1. Alarm is linked to security, management and police as required by Security Risk Assessment.

5.10.1.2. Alarm has dual pass-through communication capability.

5.10.1.3. Redundant phone and Internet lines are installed and operational.

5.10.1.4. System delivers automatic power outage notification – automatic check every 5 minutes.

5.10.1.5. Alarm system includes fire and smoke detection, monitoring and notification of fire department and facility personnel.

5.10.1.6. Pedestrian doors, overhead doors and roof access points are equipped with door contact sensors connected to an intrusion alarm system.

5.10.1.7. Roof area is monitored by motion sensors to prevent cut-and-drop intrusion.

5.10.2. Alarm Monitoring

5.10.2.1. Alarms are monitored 24/7 by bonded, accredited or certified professional security company.

5.10.2.2. Alarm triggers and breaches require a 2-minute response time or less and a clearing code process validated via phone by authorized representatives.

5.10.2.3. Monitoring includes fire and smoke detection and notification of fire department and company managers.

5.10.2.4. Automatic alarm is activated for all power outages – automatic check every 5 minutes; monitoring company provides immediate outage notification to authorized managers.

5.10.3. Motion Detection

5.10.3.1. Motion detectors are part of the security monitoring system and linked to active alarms, automatic lighting and automatic notification reporting.

5.10.3.2. Motion detection may be used to slow video recording frames per second when no motion is present to reduce digital storage requirements.

5.10.4. Panic Buttons

5.10.4.1. Panic buttons (silent alarms) are placed within sightlines of entrances/exits and in each separate physical area of the facility (e.g., office, production, storage and receiving).

5.10.4.2. Panic buttons are linked to the monitored security system.

5.10.4.3. Security Manger has established and communicated to all workers a code word for emergencies that alerts fellow workers to an active emergency.

5.10.4.4. Security training for workers includes panic-button and code-word usage instructions.

5.10.5. Alarm System Maintenance

5.10.5.1. Security manager schedules alarm system preventative maintenance at least annually by a qualified supplier to ensure continuity of coverage, check signal loss and integrity of anti-tampering features, etc.

5.10.5.2. Daily, the Security Manager or designee ensures alarm sensors and triggers are functional and alarm system is operational 24/7.

5.10.5.3. Security Manager documents video system maintenance in the Master Equipment List or similar log maintained by Security.

5.11. Video Surveillance

5.11.1. Video Monitoring

5.11.1.1. The operation has installed video monitoring equipment that satisfies all local regulations pertaining to monitoring of cannabis facilities.

5.11.1.2. The video monitoring system is equipped with an automatic failure notification system that promptly notifies management or employees if there is any prolonged surveillance interruption or failure.

5.11.1.3. Date and time is embedded on every frame of all surveillance recordings without obscuring any useable areas of the image.

5.11.1.4. An automatic battery backup system is installed to support a minimum of one hour of recording time.

5.11.1.5. The operation retains a current copy of local security laws and maintenance logs for all video surveillance equipment.

Note: FOCUS Standards provide specifications and requirements for professional-level video security surveillance – the Security Plan documents and justifies the level of equipment and depth of security processes used to meet local regulations and control facility-specific risks.

5.11.2. Video Recording Security

5.11.2.1. All video surveillance equipment and recordings are stored in a locked, secure area that is accessible only to management and authorized employees of the facility.

5.11.2.2. Digital video files are password protected and reviewed only by authorized personnel.

5.11.3. Video Quality and Coverage

5.11.3.1. Video surveillance recording system provides coverage of all internal and external areas of the facility.

5.11.3.2. Video quality allows for clear visual identification of individuals and activities on the premises.

5.11.3.3. Placement ensures camera is capable of identifying activity occurring within 20 feet of all points of entry to and exit from the registered facility.

5.11.3.4. Equipment specifications are based on operational requirements but no less than HD quality (1920 x 1080 – 2.1 megapixel).

a. External Areas: High-resolution (2048 x 1536 – 3.1 megapixel recommended) IP66-rated camera with wide dynamic range capable of recording in all lighting and weather conditions.

b. Internal Areas: Medium resolution HD; IR required for grow rooms.

5.11.3.5. Video camera coverage includes:

a. All secure and restricted access areas

b. All point-of-sale areas

c. All points of entry to or exit from secure and restricted access areas

d. All points of entry to or exit from the registered facility

5.11.4. Continuous Video Monitoring

5.11.4.1. Views of all entries, exits and secure- and restricted-access areas are continuously recorded by video surveillance equipment 24 hours a day, 365 days a year.

5.11.4.2. Adequate internal and external signage is posted stating "Premises under video surveillance" or similar.

5.11.4.3. To manage digital storage volume, cameras can be set to record low frame rate for general surveillance, then activate to high frame rate (15 fps or more) with motion activation.

a. This is the only authorized use of motion-activated camera functionality.

5.11.5. Video Retention

5.11.5.1. All video recordings are stored in a raw non-editable and unedited format that preserves it as a legitimately captured video and guarantees that no image alterations have occurred.

5.11.5.2. All surveillance recordings are retained for a minimum of 45 days and in a format that can be easily accessed for viewing.

a. Security Plan provides justification if fewer storage days retained.

5.11.5.3. Access to video recordings is password protected and limited to personnel authorized by the Security Manager.

5.11.6. Video System Maintenance

5.11.6.1. Security Manager schedules video system preventative maintenance at least annually by the operation's qualified supplier

5.11.6.2. Supplier verifies continuity of coverage and checks for signal loss, integrity of anti-tampering features, camera cleanliness and targeting.

5.11.6.3. Monthly or more often depending on environmental conditions, Security Manager or designee checks camera domes/lenses to ensure they are unobstructed, properly targeted and clean.

5.11.6.4. Security Manager documents video system maintenance in the Master Equipment List or similar log maintained by Security Manager.

5.12. Transport Security

5.12.1. Transport security procedures are contained in SOP-TRS-01 Transportation.

REFERENCES

5.13. ISO 9001:2008 Quality Management Systems — Requirements

5.14. SOP-MGT-02 Risk Management

5.15. SOP-TRS-01 Transportation

FORMS AND RECORDS

5.16. Key Log

5.17. Master Equipment List

5.18. Security Incident Report

5.19. Storage Access List

REVIEW FREQUENCY

5.20. Every two years

DISTRIBUTION

5.21. Operations Manager

5.22. Security Manager

5.23. Production Dept.

5.24. Security Dept.

5.25. SOP Library – worker access

REVISION HISTORY

Issue No.	Revision Summary	Effective Date
New	First Issue – New procedure	01.01.2017

DOCUMENT APPROVAL

	Originator:	Reviewed & Approved By:	Reviewed & Approved By:
Name			
Title			
Date			

D-2.3 By selecting **“Yes”**, the Applicant attests that the answer provided in response to Question D-2.2 is voluntarily submitted to the State Board of Pharmacy in expectation of protection from disclosure as provided by section 149.433 of the Revised Code.

YES

Operations Plan(Receiving of Product)

D-3.1 By selecting "**Yes**", the Applicant attests that it is able to safely and securely receive medical marijuana and medical marijuana products.

YES

D-3.2 By selecting "**Yes**", the Applicant attests that it will implement standard operating procedures to inspect, prior to accepting any medical marijuana. Defective products must be rejected. Defective products include, but are not limited to the following: expired, damaged, deteriorated, misbranded or adulterated medical marijuana. OAC 3796:6-3-06; OAC 3796:8

YES

D-3.3 Please describe the Applicant's processes, procedures, and controls regarding the inspection of medical marijuana from cultivators and processors prior to accepting any delivery at the proposed dispensary. Include a description of the proposed space for delivery and inspection. OAC 3796:6-3-06

[redacted]

marijuana and retain employee training attendance records.

D-3.3.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-3.3. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final D-3.3.1 Incoming Inspection Form, Product Inspection SOP.pdf**
NOTE: This applicant uploaded document is the next 13 page(s) of this document.

Incoming Inspection Form

Product Name:		**Lot/Batch #**	
Part Number:		**PO #**	
Supplier:		**Manfacturer:**	
Inspector:			
Inspection Date:			
Quantity Received:		**Sample Size:**	

Inspect all incoming materials to the product specification	**Pass**	**Fail**
Verify correct item received	☐	☐
Verify correct quantity/volume/weight received	☐	☐
Inspect item(s) using quality specifications	☐	☐
Inspect packaging and labeling for integrity and appropriateness	☐	☐
Inspect for signs of decay or degradation	☐	☐
Inspect for foreign materials or other contamination	☐	☐
Inspect for physical damage	☐	☐
Check odor for spoilage or seal breakage (as applicable to the product)	☐	☐
Verify product safety features are intact/operational	☐	☐
Verify product security requirements are followed	☐	☐

Applicable Specifications:

Sampling Plan Used:

List NONCONFORMITIES:

Document Material Review Investigation Actions and Results:

Disposition

Use As Is	☐	Release to Inventory
Deviate from Specification	☐	Authorization:
Restricted Use	☐	Restriction:
Corrective Action/Rework	☐	CA Report #:
Rejected - Return to Supplier	☐	RTN #:
Rejected - Destroy	☐	Destroyed By:
Other:	☐	Action:

Justification and Additional Directions:

Approvals

Inspector:	*Date:*
Quality Manager:	*Date:*
Production Manager:	*Date:*

1.0 SCOPE

1.1. Measurement of cannabis products and processes for cannabis production facilities.

2.0 OBJECTIVES

2.1. To outline the responsibilities, requirements and processes for cannabis product and process measurement

3.0 RESPONSIBILITIES

3.1. Management ensures all procedures are followed and evaluated.

3.2. Quality Manager (QA/QC) ensures all measurement is handled according to this procedure.

4.0 DEFINITIONS AND ABBREVIATIONS

4.1. Quality Management System (QMS) – Business and operational processes and systems implemented to ensure GAP and GMP; they include organizational structure, policies, procedures, processes, systems, controls and resources needed to ensure quality products and services.

4.2. Cannabis Product – Any cannabis-derived or cannabis-containing product that is packaged for bulk or retail distribution

4.3. Cannabis Materials – Any material that contains cannabis or cannabis-derived materials. Cannabis Materials are not necessarily packaged or labeled for bulk or retail distribution

4.4. Deviation – Any failure to meet specifications or procedures is documented as a Deviation and is reviewed by QA/QC personnel.

4.5. Official Test Report – A test report issued on company letterhead, by a laboratory that is recognized according to the binding regulatory body.

4.6. Unit of Measure – Typically, units are in metric (grams or milligrams). All packages for retail or bulk distribution must list the net quantity of product in the most accurate unit of measure (grams or ounces for weight, milliliters or fluid ounces for volume).

5.0 PROCEDURE

5.1. The Quality Manager and Quality Assurance department (QA) are responsible to ensure all products meet quality specifications prior to release for sale or use.

5.2. QA maintains systems and processes to ensure product quality, and oversees or verifies other processes (such as laboratory testing) to meet this objective.

5.3. QA reviews the overall quality management system and how the QMS is used by workers to help validate product quality systems and processes.

5.4. Customer Satisfaction

5.4.1. Quality Assurance (QA) monitors information on customer satisfaction and/or dissatisfaction as one of the measurements of performance of the QMS. QA and Management determine the methods for obtaining and using this information.

5.5. Audits

5.5.1. QA conducts periodic audits from internal or external auditors. The purpose of the audit is to determine whether the department's QMS:

5.5.1.1. Conforms to the requirements of applicable standards

5.5.1.2. Is being effectively implemented and maintained

5.5.2. Quality audits are planned and scheduled based on the importance of the activity to be audited. Trained personnel independent of those having direct responsibility for the activity being audited conduct the audits, ensuring that auditors do not audit their own work.

5.5.3. The department may arrange for the audit function to be performed by other qualified parties. Examples of other qualified parties include:

5.5.3.1. Agents of the customer, or customer's internal quality audit department

5.5.3.2. Independent third-party organizations, such as a qualified consultant or consulting firm

5.5.3.3. Qualified internal auditors from other departments

5.5.4. The results of the audits are documented and brought to the attention of the personnel responsible for the area audited. Management personnel responsible for the area take timely corrective action on the deficiencies found during the audit.

5.5.5. Follow-up activities verify and record the implementation of the corrective action, report the verification results and close out the audit. Subsequent audits verify the effectiveness of the corrective actions taken.

5.5.6. Results of internal audits and the corrective action are submitted for management review.

5.6. Monitoring and Measurement of Product

5.6.1. QA measures and monitors the characteristics of a product to verify it meets specifications and requirements.

5.6.2. QA performs or facilitates testing and inspection as required by material specifications and the operation's product testing plan.

5.6.3. Evidence of conformity with the acceptance criteria is documented on a certificate of analysis that accompanies each batch.

5.6.4. QA carries out final inspection in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to specified requirements.

5.6.5. Records indicate the position and signature of the person responsible for release of product.

5.6.6. QA approval indicates all specified inspections and tests and calibrations, including those specified on receipt or in process, have been completed and the results meet specified requirements.

5.6.7. Product release and service delivery does not proceed until inspectors have completed all the specified activities and the associated data and documentation are available unless otherwise approved by the customer.

5.6.8. QA has established and maintains records that provide evidence that products have been inspected and/or tested.

5.6.8.1. These records show clearly whether the products have passed or failed according to defined acceptance criteria in product specifications.

5.6.8.2. Where the product fails to pass any inspection or test, the operation follows SOP-QA-02 Nonconformance and CAPA.

5.6.9. Procedures indicate the processes and authority to release product for sale.

5.7. Control of Nonconforming Product

5.7.1. QA ensures that product that do not requirements are identified and controlled where possible to prevent unintended use or delivery to the customer, and corrected if delivered. This policy includes:

5.7.1.1. Identification, documentation, evaluation, segregation (where practical), disposition of nonconforming product, and for notification of the functions concerned

5.7.1.2. Assigning responsibility for the review and the authority for disposition of nonconforming product

5.7.1.3. Correction of nonconforming service and re-verification of the affected product after correction to demonstrate conformity (if necessary)

5.7.1.4. Handling of nonconforming product when it is detected after delivery to the customer

5.8. Data Analysis

5.8.1. QA collects and analyzes appropriate data to determine the suitability and effectiveness of the QMS and to identify improvements that can be made. This includes data generated by measuring and monitoring activities and other relevant sources.

5.8.2. The data are analyzed and may provide information on:

5.8.2.1. Customer satisfaction and/or dissatisfaction

5.8.2.2. Conformance of products to customer requirements

5.8.2.3. Characteristics of processes, product and their trends

5.8.2.4. Performance of suppliers

5.9. Continuous Improvement

5.9.1. QA plans and manages the processes necessary for the continuous improvement of the QMS.

5.9.2. QA facilitates the continual improvement of the QMS through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review.

5.10. Corrective Action

5.10.1. QA takes corrective action to eliminate the cause of identified nonconformities in order to prevent recurrence. Corrective actions are appropriate to the impact of the problems encountered. The following are QA responsibilities for corrective actions:

a. Identifying nonconformities (including customer complaints)

b. Determining the causes of nonconformity

c. Evaluating of the need for actions to ensure that nonconformities do not recur

d. Determining and implementing the corrective actions needed

e. Recording results of action taken

f. Review and evaluation of corrective action taken to assess its effectiveness

5.11. Preventative Action

5.11.1. QA identifies preventive actions to eliminate the causes of identified potential nonconformities to prevent initial occurrence.

5.11.2. QA analyzes appropriate sources of information, such as processes and work operations results that affect product quality, concessions, audit results, quality records, service reports and customer complaints, to detect risks and opportunities for preventive action.

5.11.3. QA ensures the preventive actions implemented are appropriate for the potential impact of the risk. The following are QA responsibilities for preventive actions:

5.11.3.1. Identification of potential nonconformities and their causes

5.11.3.2. Determination of the steps needed to eliminate identified causes and completion of the preventive action implementation

5.11.3.3. Recording results of action taken

5.11.3.4. Review and evaluation of preventive action taken to assess its effectiveness

5.11.3.5. Ensuring that relevant information on actions taken, including changes to procedures, is subject to management review

5.12. Product Testing Plan

5.12.1. The operation ensures all products sold or transferred are free from contaminants and adulterants as specified in the product testing plan and/or product specification.

5.12.2. QA oversees product testing, including onsite inspections and reviews and offsite testing at qualified laboratories.

5.12.3. The operation develops a testing plan that addresses all risks to products.

a. Testing is done on all batches and final products.

b. All test reports reference the corresponding batch.

c. Test results must match batch/lot and date produced.

d. Test results are provided with all final products.

e. Supplier-provided test results must be from a certified lab and are checked for accuracy.

f. Test results are retained for all raw cannabis and cannabis-derived products for three years.

5.12.4. A qualified QA representative reviews all test lab reports to ensure:

a. Testing laboratory is certified to ISO 17025, FOCUS Standard or equivalent

b. Test report lists batch/lot number that matches product tested

c. The report is complete:

1. Date
2. Methodology performed and method reference
3. Lab technician(s) signature or code
4. Complete data provided
5. Equipment protocol data provided (equipment and methods)

5.12.5. All test standards are subject to federal, state and local laws and regulations.

5.13. Sampling Procedures

5.13.1. The operation samples products for testing according to a sampling plan that is required by applicable regulations and/or is scientifically valid.

5.13.2. Sampling meets laboratory criteria and established industry standards.

5.13.3. The sampling log lists the batch or lot number, sampling date, name/description of sample and initials of person performing the sampling.

5.13.4. Samples are ensured by the operation to be sufficiently homogenous and representative of the product sold.

5.13.5. Samples are retrieved, stored and transported in original, clean packaging and packaged in a way that preserves the composition of the sample.

5.13.6. Samples must be sealed with tamper-evident tape or seal. Seals are only broken by an authorized person.

5.13.7. Records of sampling, laboratory data and other documents are kept on file for review for three years from test date.

5.14. Incoming Goods Inspection

5.14.1. Goods are inspected for (as applicable to the product):

a. Correct item

b. Correct quantity and/or weight (use calibrated scale)

c. Meets quality specifications

d. Signs of decay or degradation

e. Foreign materials contamination

f. Odor

g. Physical damage

h. Improper packaging or mislabeling

i. Product safety

j. Security issues

5.14.2. All nonconformances are documented according to the Nonconformance SOP.

5.14.3. Recordkeeping for incoming goods:

a. Incoming inspection logs and raw material inventory report is kept on file for review.

b. All raw materials are entered into the inventory list when received and when released to production.

c. The operation retains all product certificates of analysis, specifications, test reports, supplier information, purchase orders, invoices, quality statements and certifications, letters of guarantee and other supplier documentation for all raw materials, ingredients, cannabis extracts, etc., used in the process.

d. Incoming goods documentation is retained for at least three years.

5.15. Independent Laboratory Testing

5.15.1. The operation has a written procedure for laboratory approval.

5.15.2. The operation uses testing laboratories that meets ISO 17025 or equivalent, the FOCUS Laboratory Standard or relevant state cannabis test lab standard. If a lab meeting ISO 17025 is not available, operation maintains documentation to validate the laboratory methods that were used.

5.15.3. The operation retains valid certification documents for all testing labs used.

5.16. General Testing Procedures

5.16.1. The operation has product specifications which document threshold limits for the presence of biological, chemical and physical contaminants.

5.16.2. All products must be tested to verify specification was met.

5.16.3. Products found to not meet specification may not be approved for sale without Material Review.

5.16.4. Test methods and results meet federal, state and local regulations and limits, which may supersede the limits listed below:

5.16.4.1. Test reports provide method references and data for all tested and detected solvents.

5.16.4.2. The test report lists the solvents that were not or could not be tested.

5.16.4.3. If a test method's limit of detection is above the specified limit for a solvent, the limit should be reviewed by a scientific or regulatory expert to determine if the method is suitable for its intended purpose.

5.16.4.4. Tolerance limits and test methods are part of product specifications, and in order to be changed must undergo document change control.

5.16.5. Limits adhere to all applicable regulations.

5.16.6. Limits are stated in commonly understood units of measure, such as parts per million (PPM or ppm) or colony-forming unit (CFU or cfu).

5.17. Microbiology

5.17.1. All products must be tested for total aerobic plate count, yeast and mold, and all applicable pathogens (E. coli, Salmonella) using methods recognized by AOAC International or other recognized standards

5.17.2. The threshold limit for E. coli or Salmonella is less than one colony forming unit (CFU) per gram of tested material.

5.18. Solvent and Chemical Residue

a. Acetone < 1 ppm

b. Benzene < 0 ppm

c. Butane and Heptane < 50 ppm

d. Hexane < 10 ppm

e. Polyacrylonitrile (PAN) < 1 ppm

f. Polycyclic Aromatic Hydrocarbons (PAHs) < 1 ppm

g. Toluene < 1 ppm

h. Total Xylenes < 1ppm

i. Solvent-extracted products made with Class 3 or other solvents (ethanol, acetone, ethyl acetate) must not exceed 0.5% residual solvent by weight or 50 parts per million (ppm) per one gram of solvent-based product.

j. Products labeled as "Organic" must meet the NOP requirements, and not be processed with any solvents other than water, CO2 or certified organic ethanol.

5.19. Heavy Metals

5.19.1. Testing for heavy metals includes lead, arsenic, cadmium and mercury.

5.19.2. Test methods and results meet applicable regulations, which may supersede the following suggested limits:

a. Lead < 6 ppm

b. Arsenic < 10 ppm

c. Cadmium < 4.1 ppm

d. Mercury < 2.0 ppm

5.20. Pesticide Residue

5.20.1. The operation's specifications for product content of pesticide residues meets applicable regulations.

5.20.2. The operation tests all product batches for pesticides, or according to a statistically valid testing plan.

5.20.3. Results for residue must be within limits specified in federal, state and local regulations. Where not specified, 0.1 ppm or a positive result at the limit of quantification is considered to exceed safe residue limits.

5.21. Potency and Cannabinoid Profile

5.21.1. The operation tests products for cannabinoid profiles and provides results for levels of THC, THC-A, CBD, CBD-A, CBN, as applicable to the product specification.

5.21.2. Terpenes may be tested if listed on the specification.

5.22. Contaminants and Filth

5.22.1. The operation must visually inspect all products for contaminants and filth.

a. Contaminants include any biological or chemical agent, foreign matter, or other substances not intentionally added to products that may compromise food safety or suitability.

5.22.2. Thresholds for physical contaminants may be listed on the product specification.

5.22.3. Inspection records indicate a visual inspection has taken place for all batches.

5.23. Stability Testing

5.23.1. The operation may perform stability/shelf life testing as dictated by the nature and usage of the product.

5.23.2. Test results and analysis must be retained.

5.24. Test Results Analysis

5.24.1. All products with pending tests are quarantined until test results are received and reviewed. Containers must include batch/lot code for tracking.

5.24.2. A qualified staff member reviews each test result against the product specification. If the product meets all specifications, the staff member shall release the batch of product to the next step in the process.

5.24.3. A product that fails to meet specifications undergoes investigation. A retest may be conducted as a result of the investigation. Retest results, if within specification, must be supported by a scientific rationale to be accepted over the original results.

5.24.4. Reduced testing frequency may be permitted if statistical data supports a very low risk of contamination.

5.25. Sample Retention

5.25.1. The operation retains at least 2 samples of product from each production batch in a restricted area.

5.25.2. All product samples are kept in storage for three years after manufacture date.

5.25.3. Any sample involved in a pending claim or legal dispute is not destroyed.

5.26. Records

5.26.1. All inspection, testing and other product measurement records are retained for at least three years after the test date.

5.26.2. Certificates of analysis, test reports and sample logs list the batch/lot, product name and test or sampling date.

6.0 REFERENCES

6.1. ISO 9001:2008 Quality Management Systems — Requirements

6.2. SOP-QA-01 Quality Management

6.3. ISO 9001:2008 Quality Management Systems — Requirements

6.4. ISO 17025 Quality Management Systems for Analytical Laboratories

6.5. 21 CFR 117 Food GMP

6.6. 21 CFR 111 Dietary Supplement GMP

6.7. SOP-QA-02 Nonconformance and CAPA

7.0 FORMS AND RECORDS

7.1. Laboratory Qualification SOP and Form

7.2. Sampling Log

7.3. Testing Result Checklist

7.4. Material Approval Form

7.5. Material Review Form

7.6. Corrective Action Report

REVIEW FREQUENCY

7.7. Every two years.

DISTRIBUTION

7.8. Managers and Supervisors

7.9. QA Department

7.10. SOP Library – worker access

REVISION HISTORY

Issue No.	Revision Summary	Effective Date
New	First Issue – New procedure	03.31.2017

DOCUMENT APPROVAL

	Originator:	Reviewed & Approved By:	Reviewed & Approved By:
Name			
Title			
Date			

Operations Plan(Storage of Product)

D-4.1 There will be separate, locked, limited access areas for the storage of medical marijuana that is expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached, until the medical marijuana is returned to a cultivator, or processor, destroyed or otherwise disposed.

YES

D-4.2 All storage areas will be maintained in a clean and orderly condition and free from infestation by insects, rodents, birds, and pests.

YES

D-4.3 A separate and secure area for temporary storage of medical marijuana that is awaiting disposal will be established.

YES

D-4.4 Please describe the Applicant's plans regarding the storage of medical marijuana within the proposed dispensary. The plan should include, but is not limited to, descriptions of the following:

1. Oversight of medical marijuana storage
2. Physical security measures
3. Record maintenance
4. Persons who will have access to medical marijuana
5. Climate control and lighting maintenance, including any necessary equipment
6. Sanitation of storage areas

Please reference OAC 3796:6-3-07 for more information.

[redacted]

[redacted]

D-4.4.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-4.4. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final D-4.4.1 Storage Inventory, Sanitation Schedule, Storage SOP.pdf**
NOTE: This applicant uploaded document is the next 17 page(s) of this document.

Date	Product Number	Product Name	Batch Number

Storage Inventory Log

Indicate Quanity Added or Removed

Add /Remove	Quantity	Reason	Location

Worker

Master Sanitation Schedule

Area/Equipment/Item	Cleaning Frequency	Cleaning Agents

Revision: 03.31.17

Location of Equipment

1.0 SCOPE

1.1. Storage of cannabis products and materials

2.0 OBJECTIVES

2.1. To outline the responsibilities, requirements and processes for storing cannabis products and materials.

3.0 RESPONSIBILITIES

3.1. Management ensures all facilities, equipment and procedures are implemented to safely and securely store cannabis products and materials.

3.2. Quality Manager (QA) ensures all processes are followed and documented.

3.3. Receiving and Inventory Control workers follow all procedures.

4.0 DEFINITIONS AND ABBREVIATIONS

4.1. Identity – product contains the properties and solutions described on the container label or other information in the packaging

4.2. Materials – Any materials used in production, includes all components, raw materials, packaging and finished packaged products

4.3. Quality Assurance – includes the review and approval of all procedures related to storage and transportation, and review of associated records

5.0 PROCEDURE

5.1. Materials Storage

5.1.1. Incoming materials are inspected according to the Receiving Inspection SOP

5.1.2. All materials are stored in a clean and dry environment to preserve their identity, strength, purity and quality.

5.1.3. All storage areas are constructed of easily cleaned materials (non-porous, non-toxic) and with limited unreachable, difficult-to-clean areas.

5.1.4. All materials are stored a minimum of 6 inches off the ground.

5.1.5. Air filters or scrubbers are installed and used as appropriate to eliminate odors.

5.1.6. All stored materials are labeled with an accurate statement of identity and a unique identifier code (lot number) for the material.

5.1.7. All materials are recorded in the inventory system.

5.1.8. All storage areas are clean, well ventilated and free from condensation, sewage, dust, dirt, chemicals or other contaminants.

5.1.9. Stored products and packaging are clean and free from dust, debris and contaminants.

5.1.10. Cleaning schedules and logs are current and retained for review; product is protected or removed during cleaning.

5.1.11. Special storage areas such as flammable stores, cold rooms or low humidity rooms are provided for materials that require these conditions. The environment for special storage areas are continuously monitored and equipped with an alarm system.

5.1.12. There is sufficient space for proper segregation of the various categories of materials and products, to ensure control of food allergens.

5.1.12.1. Delivery, acceptance and dispatch areas should protect materials and products from the weather.

5.1.12.2. Delivery areas are designed and equipped to allow incoming material containers to be cleaned prior to storage.

5.1.13. Warehouses that are not computer controlled should provide separate areas clearly labeled for the following categories of material, as applicable: sampling, quarantined, raw, packaging, intermediate, finished products, rejected, recalled and returned materials or products.

5.1.14. A separate sampling area for starting materials is provided. If sampling is performed in the storage area, it is conducted in such a way as to prevent contamination or cross-contamination.

5.1.15. Printed packaging materials and highly potent or toxic substances are controlled and kept under safe and secure conditions.

5.1.16. The weighing of materials is carried out in separate weighing areas designed for that use, e.g., with provisions for dust control.

5.1.17. Racks provided for the storage of packaging are constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas are constructed to prevent packaging from becoming a harborage for pests or vermin.

5.2. Cannabis Storage

5.2.1. All areas where cannabis or cannabis-derived products are stored are locked and secure with access restricted to authorized personnel.

5.2.2. Cannabis product storage areas must only be used to store raw cannabis, components of cannabis products, final cannabis products, and packaging and labeling related to cannabis products.

5.2.3. All products added or removed to the inventory system are recorded.

5.2.4. Signage must indicate "Restricted Access – Authorized Personnel Only" or equivalent.

5.2.5. The operation uses a sign in/sign out log or automatic RF tracking system. All access logs are retained for two years.

5.2.6. Containers are sealed with tamper-evident seals or packaging that records the worker who sealed the container and the seal date, at a minimum.

5.3. Quarantined Material

5.3.1. Segregation is required for the storage of rejected, recalled or returned materials or products.

5.3.2. An area is designated and controlled for quarantined material and products. The area is contained, locked, marked with clear signage and access is limited by to authorized personnel.

5.3.3. Quarantined products and materials are labeled on the container/packaging and tracked in production records.

5.3.4. Quarantined containers bear distinguishing labels to ensure they are not mixed with other material.

5.3.5. All quarantined material is dispositioned within 30 days and recorded in the inventory system.

5.3.5.1. Longer quarantine storage requires justification and approval by the Quality Manager.

5.4. Product Transfers

5.4.1. If allowed by state and local laws and regulations, a licensed operation may transfer (sell/purchase) usable cannabis or cannabis plants to another licensed cannabis operation.

5.4.1.1. Both operations must document the transaction using a transfer manifest.

5.4.1.2. Material is sampled, tested and analyzed for product quality prior to transfer according to Sampling SOP and Measurement SOP.

5.4.1.3. Receiving agent must enter all product transfers into the inventory control system.

5.4.1.4. Operation must retain records of all product transfers for two years.

5.4.1.5. Cannabis transfers must have the following information documented:

a. Name and address of seller and buyer
b. Transfer manifest authorizing the transfer
c. Unique product code or SKU
d. Supplier batch, lot or control number
e. Weight in metric units (all usable cannabis)
f. Amount (number of plants) received
g. Date of manufacture or processing
h. Date of receipt
i. Amount of finished products received including, as applicable, the weight in metric units or the number of units
j. Strain identification; traceability; certificates of strain analysis or similar documentation
k. Product test data from a certified laboratory
l. Certificate of Analysis – product specifications
m. Harvest specifications including chemicals added during cultivation
n. Transferring agent's registration card and expiration date
o. Transfer and transportation subject to all requirements for Transport Security

6.0 REFERENCES

6.1. ISO 9001:2008 Quality Management Systems — Requirements

6.2. SQF Code, Version 7

6.3. 21 CFR 117 Good Manufacturing Practices for Food

6.4. WHO GMP for Medicines

6.5. SOP-QA-01 Quality Management

6.6. SOP-MAT-02 Receiving

6.7. SOP-SEC-01 Security

6.8. SOP-TRS-01 Transportation

7.0 FORMS AND RECORDS

7.1. Cannabis Storage Inventory Log

7.2. Cannabis Storage Access Log

7.3. Environmental Controls Log

7.4. Storage Area Cleaning Log

8.0 REVIEW FREQUENCY

8.1. Every two years.

9.0 DISTRIBUTION

9.1. Operations Manager

9.2. Security Department

9.3. Inventory Control

9.4. Receiving

9.5. Shipping

10.0 REVISION HISTORY

Issue No.	Revision Summary	Effective Date
New	First Issue – New procedure	03.31.2017

11.0 DOCUMENT APPROVAL

	Originator:	Reviewed & Approved By:	Reviewed & Approved By:
Name			
Title			
Date			

Operations Plan(Dispensing of Product)

D-5.1 By selecting "**Yes**", the Applicant attests that it is prepared and willing to join the American Society for Automation in Pharmacy (ASAP) annually in order to facilitate near-real-time reporting to the Ohio Automated Rx Reporting System (OARRS). American Society for Automation in Pharmacy; OAC 3796:6-3-08; OAC 3796:6-3-10

YES

D-5.2 By selecting "**Yes**", the Applicant attests that it will use the patient registry to verify the registration of a patient or caregiver. OAC 3796:6-3-08

YES

D-5.3 Please indicate the expected number of Patient Registry scanners needed for the Applicant's facility (Information Only).

Three

D-5.4 By selecting "**Yes**", the Applicant attests that it will have at least two employees physically present at the dispensary location, one of whom is a dispensary key employee, when the dispensary is open for the sale of medical marijuana. OAC 3796:6-3-03

YES

D-5.5 Please describe the Applicant's processes, procedures, and controls regarding the dispensing of medical marijuana, updating the patient record, and product labeling. Describe how these will be supported by the Applicant's internal inventory system including integration with the state inventory tracking system and for reporting to OARRS using the current ASAP format. Please attach a sample product label, with any identifiable information redacted or anonymized. OAC 3796:6-3-08; OAC 3796:6-3-09; OAC 3796:6-3-10

The dispensary is authorized to and will only sell or transfer medical marijuana to qualified patients or laboratories licensed under Chapter 4729-13 of the Administrative Code to possess dangerous drugs and controlled substances for scientific and clinical purposes. The dispensary will sell medical marijuana to patients and caregivers only in a direct, face-to-face exchange, using whole day increments. This is important as it allows staff to evaluate abuse and diversion potential. Associated key employees will exercise their judgment in determining whether to dispense medical marijuana to a patient or caregiver. If there is suspicion of potential negative health consequences for the patient or public, or when the patient is exhibiting signs of abuse or diversion; services will be withheld. If such a determination occurs, it will be reported to the state board of pharmacy within twenty-four hours. Prior to the sale of medical marijuana, employees will verify the patient or caregiver's state registration information by scanning the patient or caregiver's driver's license, or United States passport and verifying the following information is complete and correct:

• Patient full name address and telephone number
• Patient date of birth
• Patient qualifying condition
• State-issued identification number
• Patient registration number
• Physician's full name and DEA registration number
• Physician's medical license number

• Physician's state issued certificate to recommend
• Date the recommendation was issued
• Physician's business address, telephone number, and email address;
• Indication whether the recommendation is new or a renewal
• Number of the refill being dispensed, if applicable; and
• Date written recommendation was issued.

For new patients, associated key employees will create a new patient profile containing the following information:
• Dispensary certificate of operation number
• Dispensary name, address and telephone number
• Date the medical marijuana is being dispensed
• Order number
• Quantity
• Days' supply
• Product identifier;
• Payment code for either cash or third-party provider; and
• Brand name of the medical marijuana.

After confirming all required information is correct, and that the patient or caregiver has not met or exceeded their 90-day supply or possession limit; key associated employees will dispense medical marijuana as determined by the patient’s recommending physician. All products will be dispensed in unmarked, opaque packaging. Each container or package containing medical marijuana will be labeled with:
• The license number of the marijuana cultivator as well as their corresponding business or trade name
• Product identifier
• Date and quantity dispensed, including the net weight measured in ounces and grams or by volume, as appropriate;
• Patient name and registry number and, if applicable, the name of the designated caregiver;
• Dispensary name, address and license number;
• Cannabinoid profile, concentration levels and terpene profile
• "This product may cause impairment and may be habit-forming";
• "This product may be unlawful outside of the State of Ohio";
• Date marijuana was harvested.

If the product is in a form other than plant material, the following will also be included on the label:
• Date the product was manufactured
• Name and license number of the manufacturer
• List of all ingredients
• List of all major food allergens as identified in 21 US Code 343;
• "Caution: When eaten or swallowed, the effects and impairment caused by this drug may be delayed;" and
• Type of extraction process and any solvent, gas or other chemical used in the extraction process or any other compound added to the extract used.

All products will be dispensed with the following information printed in twelve-point font, no italics:
• Disclosure of pesticide applied to the marijuana plants,
• The growing medium used during cultivation
• The toll-free telephone line for patient, caregiver, and health professional medical marijuana inquiries and the following warnings:
• "Warning: This product may cause impairment and may be habit-forming. Smoking medical marijuana

is not permitted in the State of Ohio."
• "There may be health risks associated with consumption of this product."
• "Should not be used by women who are pregnant or breastfeeding."
• "For use only by the person named on the label of the dispensed product. Keep out of reach of children."
• "Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug."
• "If you have a concern that an error may have occurred in the dispensing of your medical marijuana, you may contact the State of Ohio Board of Pharmacy, using the contact information found at medicalmarijuana.ohio.gov."

The dispensary will transmit electronically to Ohio Automated Rx Reporting System (OARRS) the information below within five minutes of the dispensing of any and all medical marijuana:
• Dispensary's license number
• Dispensary name, address and telephone number
• Patient: full name, registry identification number, residential address, telephone number, date of birth and gender
• Recommending physician's full name and DEA identification number
• Date recommendation was issued by the recommending physician
• Indication whether the recommendation is new or refill
• Refill number, if any
• Date order filled
• Order number
• Quantity
• Days' supply
• Product identifier
• Date order written
• Payment code, and
• Brand of medical marijuana.

The dispensary's internal inventory system will be compatible with and capable of integrating with the state inventory tracking system. This allows dispensary staff to use a scanner approved by the state board of pharmacy to retrieve patient registry data by scanning registry identification cards and government issued photo identification. The internal inventory management system will also maintain a record of each sale, purchase and return of medical marijuana in the inventory tracking system established pursuant to section 3796.07 of the Revised Code. All required dispensing information will be transmitted to the board of pharmacy in the format specified by the American Society for Automation in Pharmacy (ASAP), for prescription monitoring systems. Annual registration with ASAP will be maintained in order to automate reporting to OARRS. The dispensary's internal inventory control and point of sale systems, will be responsible for generating ASAP 4.2A files through integration with METRC as outlined in the requirements of chapter 3796:6-3. The files will be submitted to the Prescription Monitoring Program Clearinghouse so that the information is available in OARRS.

The dispensary will submit all medical marijuana dispensing information to the drug database in an accurate and timely manner.
When no drug has been dispensed over any twenty-four-hour period the dispensary will submit a "zero report" to the board of pharmacy. As a service to industry, the board will automatically generate a "zero report" for non-business days using electronic information provided by the dispensary indicating normal business hours if not open daily.
Dispensing and "zero report" shall be consecutive and inclusive from the last date and time that information was submitted and shall be reported no later than thirty-six hours after the last time

reported on a previous report. The responsible key employee will notify the board of pharmacy in writing if the dispensary ceases to possess medical marijuana for distribution. The board will also be notified when the dispensary resumes dispensing. If an omission of dispensing information occurs for any reason, the dispensary will submit the corrected information to the state board of pharmacy in the next reporting period. All data will be transmitted in compliance with all federal and state laws, including the federal Health Insurance Portability and Accountability Act (HIPPA) of 1996, Public Law 104-191.

D-5.5.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-5.5. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final D-5.5.1 Mock Label, Packaging and Labeling SOP.pdf**
NOTE: This applicant uploaded document is the next 12 page(s) of this document.

PATIENT #	
PRODUCT BARCODE	
PRODUCT NAME	
PRODUCT WEIGHT	
BATCH #	
DISPENSARY NAME	
DISPENSARY ADDRESS	
DISPENSARY LIC #	
DATE	
HARVEST DATE	
MANUFACTURE DATE	
PROCESSOR LIC #	
INGREDIENTS	
SOLVENT USED	
CBD %	
THC%	
CBN%	
TERPENE %	
For use only by the person named on the label of the dispensed product. Keep out of reach of children	
This product may cause impairment and may be habit-forming	
This product may be unlawful outside of the State of Ohio	
Warning: This product may cause impairment and may be habit-forming. Smoking medical marijuana is not permitted in the State of Ohio	
For use only by the person named on the label of the dispensed product. Keep out of reach of children	

1.0 SCOPE

1.1. Handling, packaging and labeling cannabis products.

2.0 OBJECTIVES

2.1. Outline the responsibilities, requirements and processes for handling, packaging and labeling cannabis products.

3.0 RESPONSIBILITIES

3.1. Management ensures all procedures are followed and evaluated.

3.2. Quality Manager (QA/QC) ensures all packaging is handled according to this procedure.

3.3. Packaging and Labeling Workers – Understand and follow all procedures.

4.0 DEFINITIONS AND ABBREVIATIONS

4.1. Package (verb) – to process and/or place cannabis or cannabis-derived product into packaging for bulk or retail distribution.

4.2. Packaging – materials for containing or holding or packaging cannabis products.

4.3. Cannabis Product – Any cannabis-derived or cannabis-containing product that is packaged for bulk or retail distribution.

4.4. Cannabis Materials – Any material that contains cannabis or cannabis-derived materials. Cannabis Materials are not necessarily packaged or labeled for bulk or retail distribution.

4.5. Deviation – Any failure to meet specifications or procedures shall be documented as a Deviation, and will be reviewed by QA/QC personnel.

4.6. Official Test Report – A test report issued on company letterhead, by a laboratory that is recognized according to the binding regulatory body.

4.7. Unit of Measure – Typically, units are in metric (grams or milligrams). All packages for retail or bulk distribution will list the net quantity of product in the most accurate unit of measure (grams or ounces for weight; milliliters or fluid ounces for volume).

5.0 PROCEDURE

5.1. General Precautions

5.1.1. Cannabis packaging materials are received, identified, stored, handled and approved according to the Receiving SOP.

5.1.2. Packaging components and processes are inspected and evaluated to ensure they maintain the identity, purity, strength, and composition of the packaged products.

5.1.3. Packaging components that contact products are food grade, safe, non-reactive and suitable for their intended use.

5.1.4. Packaging procedures and related actions generally occur throughout the process of receipt, identification, processing, storage, handling, and approval of packaging, labeling and cannabis products.

5.2. Packaging and Labeling Specifications

5.2.1. Each batch of materials and packaging is traceable to their source.

5.2.2. Documentation includes receipt of materials and packaging.

5.2.3. Specific label language and packaging requirements vary by jurisdiction.

5.2.4. Packaging specification identifies appropriate materials and conditions that protect product during handling and packaging.

5.3. Packaging Documentation Protocol

5.3.1. Packaging is part of the batch record that includes:

5.3.1.1. Identity of product and description

5.3.1.2. Identity of each packaging component

5.3.1.3. Images or drawings of package and label (or reference to one)

5.3.1.4. The following are required, and their specific procedure may be part of the discretion of the operation:

a. Inspection of packaging equipment before and after use to assure that all products and packaging materials from previous operations have been removed

b. Assignment of a quantity of labels to the particular batch

c. Signature of responsible person approving the packaging meets specification and protocol

d. Monitoring of packaging steps

e. Additional applicable procedures to be followed, if any

5.3.2. Potency and purity results are listed as reported by the analytical laboratory on an official test report. Products are not labeled to contain a higher potency than found in an official test report.

5.3.3. The batch record documents that product specifications are consistently met.

5.4. Receiving Inspection:

5.4.1. All packaging containers are inspected upon receipt for appropriate labeling of contents, including broken seals or damage.

5.4.2. Supplier documentation is examined to ensure the packaging components and packing list match the purchase order.

5.4.3. Each packaging container is identified with a unique identifier such as lot or batch number.

5.4.3.1. The unique identifier allows the lot to be traced backward to the supplier, and is linked in company records with the date received.

5.4.3.2. The unique identifier is used in all batch and disposition records to ensure full traceability.

5.4.4. Labels and other packaging components are stored under quarantine until they have been examined and approved or rejected by quality control personnel.

5.5. Packaging Approval

5.5.1. Each lot of packaging components is withheld from use until the lot has been reviewed and released for use by Quality Assurance staff.

5.5.2. Inspectors validate compliance of the lot with established specifications through inspection of the components received, and a review of the specifications and supplier documentation.

5.5.3. QA approves and releases packaging components into production if they meet specifications.

5.5.4. Any packaging component that does not meet its specifications, including any incorrect labeling, is rejected by Quality Assurance personnel.

5.5.4.1. QA personnel may approve a treatment or other deviation that will render the packaging component suitable for use.

5.6. Product Labeling Requirements:

5.6.1. Each container of component, packaging component, in-process material, and product is identified at all times with the following:

5.6.1.1. Identity (part number/name) of the item

5.6.1.2. Batch or lot number

5.6.1.3. Disposition (e.g., quarantined, in-process, approved, recalled, rejected)

5.6.2. Product packages that are held in unlabeled condition for future labeling operations are identified and handled to prevent mislabeling of individual containers, lots, or batches. Identification not applied to each individual container must be sufficient to determine the identity of the product, quantity of contents, and batch, lot, or control number of each container.

5.6.3. Labels may be:

5.6.3.1. Affixed to the individual container or to an appropriate grouping of containers; or

5.6.3.2. Assigned to a defined physical location of the container(s).

5.6.4. All product labels list the following, as required by the product specification and applicable regulations:

a. Name of the business

b. Product name or identity

c. Net quantity of contents

d. Active ingredients (cannabinoid/terpene profiles)

e. Directions for use

f. Warnings

g. Common allergens

h. Instructions for appropriate storage

i. Additives, solvents or carriers used in processing

j. Inputs used in cultivation process (pesticides, fertilizers)

k. Statements or information required by state or local regulations

l. Perishable products display a “Use By” date. Shelf life is supported by data.

m. Approved test methods and laboratories

n. Date of manufacture

o. Unique identifier code (Lot number)

5.7. Warning Labels

5.7.1. All products and packaging display warnings appropriate for the product as defined in the product specification and by applicable government regulations.

5.7.2. Warning labels include the following as required:

a. This product is infused with cannabis and/or cannabinoids.

b. This product is intended for use by adults 21 years and older. Keep out of reach of children.

c. There may be health risks associated with the consumption of this product.

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

e. There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding or planning on becoming pregnant.

f. Do not drive a motor vehicle or operate machinery while using this product.

g. This product was produced without federal regulatory oversight for health, safety or efficacy.

h. This product may be habit forming.

i. This product is unlawful outside the State of (insert appropriate state).

j. Do not use with (list of contraindications).

k. Ask a doctor before use if you have (list of conditions or symptoms).

l. Ask a doctor before use if you use or eat (list of drug/drug or drug/food interaction warnings).

m. Stop use and ask a medical professional if you experience (list toxicity or other biological reactions).

n. Other warnings that may apply: allergic reaction, asthma alert, flammability, choking/water soluble gum and sore throat.

5.8. Cannabis-Infused (Edible) Product Labels

5.8.1. For all cannabis-infused products, the operation follows the FDA Food Labeling Guide to maximum extent possible to include a “Nutrition Facts” box listing:

5.8.1.1. Name of product

5.8.1.2. Net quantity, weight or volume of contents

5.8.1.3. Ingredient list

5.8.1.4. Cannabis ingredients with cannabinoid content and total weight (in mg) of THC and CBD per serving

5.8.1.5. Food allergen information

5.8.1.6. Nutritional information, for any of the following greater than 1% of the recommended daily allowance (RDA) per serving:

a. Total calories and fat calories

b. Total fat, saturated fat and trans fat

c. Cholesterol

d. Sodium

e. Total carbohydrates

f. Dietary fiber

g. Sugars

h. Protein

i. Vitamins A, C and D

5.8.2. Food Claims: nutrient content, health, qualified health and structure/function claims must comply with FDA Food Labeling Guide.

5.8.3. Edible cannabis infused products must display warning labeling on the outside of the packaging including "WARNING: MEDICAL/ADULT USE PRODUCT – KEEP OUT OF REACH OF CHILDREN" in bold capital letters, in a font size larger than the font size of the other printing on the label.

5.9. Exit Packaging

5.9.1. The operation appropriately packages all finished goods to protect product quality and prevent accidental or unauthorized use as defined by packaging specifications.

5.9.2. Each exit package displays an accurate, complete label as required by the product specification and applicable regulations.

5.9.2.1. Exit packaging labels do not conflict with the label on other (inner) packaging.

5.9.2.2. Labels and packages comply with federal, state and local regulations.

5.10. Child Resistant Packaging

5.10.1. The operation ensures every exit package containing cannabis or cannabinoid product is child resistant as defined by the Poison Prevention Packaging Act and 16 CFR 1700 — Poison Prevention Packaging.

5.10.2. Packaging must be significantly difficult for children under 5 years of age to open or to obtain a toxic or harmful amount of the substance within a reasonable time; it should also not be difficult for normal adults to reasonably access or use the product properly.

5.10.3. For elderly or disabled persons unable to open special packaging, the operation may package substances in noncomplying packaging if:

a. Complying packaging is also supplied.

b. Noncomplying packages are conspicuously labeled to indicate they should not be used in households where children are present.

5.11. Tamper Evident Packaging

5.11.1. The operation packages a product in a tamper-evident package as per applicable regulations, or if the product is or might be physically accessible to consumers prior to a sales transaction.

5.11.2. A tamper-evident package has one or more indicators or barriers to entry that, if breached or missing, provide visible evidence of tampering to consumers.

5.12. Storage and Handling

5.12.1. Materials, packaging and products are handled, stored, and distributed in a manner to avoid deterioration, prevent contamination, and avoid material mingling errors.

5.12.2. Appropriate conditions of temperature, humidity, and light are established and maintained to meet these requirements

5.12.3. Containers of materials, packaging and products are stored separately from one another, away from non-food-grade substances, not in contact with the floor and suitably spaced to permit cleaning and inspection.

5.12.4. All materials, packaging and components that are derived from wheat, soy, corn, dairy, shellfish, fish, peanuts or tree nuts are labeled as food allergens and stored accordingly.

5.12.5. Materials and products that are in liquid or aqueous form, or can support the rapid growth of microorganisms detrimental to human health, are packaged and stored in a manner that prevents a food safety hazard.

5.12.6. All packaging, labels, cannabis, cannabis-derived products and cannabis waste are stored in restricted areas.

5.12.7. All components, materials and products are used or distributed according to first-in, first-out (FIFO)

5.13. Quarantine of Materials and Packaging

5.13.1. The following are conditions that trigger the quarantine or "hold" of materials or packaging:

5.13.1.1. Newly received components and packaging components for use in manufacturing, packaging and/or labeling are considered in quarantine until they are approved by QA for production

5.13.1.2. Batches newly completed in production

5.13.1.3. Product returned to the operation for any reason

5.13.1.4. Components, packaging components, in-process materials, or products that are or may be contaminated or adulterated

5.13.1.5. Components, packaging components, in-process materials, or products that are under investigation by quality control personnel for any other reason

5.13.2. Rejected materials, packaging and products are appropriately held in a restricted access area pending destruction or other disposal.

5.13.3. Cannabis waste from packaging operations is destroyed in a manner that prevents unauthorized use.

5.13.3.1. Excludes cannabis and cannabis-derived product that is rejected and returned to the vendor.

5.13.3.2. Excludes rejected labels and other labeling.

5.13.4. Destruction of any cannabis waste is documented and witnessed by at least two personnel, one of whom is supervisory, managerial or quality control personnel; if video surveillance is used, only one worker is necessary.

5.14. Recordkeeping

5.14.1. Materials and packaging inventory

5.14.1.1. Manufacturing, packaging, labeling and holding operations keep written records for each shipment of component, packaging component, cannabis and cannabis-derived product received from another company or individual.

5.14.1.2. Records maintained include the following:

a. Identity of the received item and product or lot code
b. Supplier or vendor
c. Original cultivation operation, processing operation, or manufacturing operation, if known
d. Cultivator and supplier's batch, lot, or control number, if known
e. Date of receipt
f. Shipment delivery method and carrier

5.15. Reconciliation

5.15.1. Records of receipt, use or distribution, return and disposal of each lot of materials, packaging or products are kept chronologically, and the quantities are recorded with an appropriate level of precision.

5.15.2. After each batch or lot is used or distributed, workers reconcile the quantity received into storage against the quantity used, distributed, returned and/or disposed. Such calculations may be done using a spreadsheet or calculated and verified by separate staff.

5.15.3. QA has established reasonably narrow limits for the amount of allowed variation in the reconciliation.

5.15.4. When a reconciliation falls outside the allowed limits, quality control personnel conduct an investigation to determine the source of the discrepancy. The reconciliation is documented as a deviation which requires approval by the QA manager.

5.16. Record Retention

5.16.1. Operations retains the records required by this procedure for a period of at two years past record creation date.

6.0 REFERENCES

6.1. ISO 9001:2008 Quality Management Systems — Requirements

6.2. 21 CFR 117 Food GMP

6.3. FDA Food Labeling Guide

6.4. 21 CFR 111 Dietary Supplement GMP

6.5. State and Federal Regulations

6.6. 21 CFR 211.132 — Tamper-Evident Packaging Requirements for Over-the-Counter (OTC) Human Drug Products

6.7. Poison Prevention Packaging Act and 16 CFR 1700 — Poison Prevention Packaging.

6.8. SOP-QA-01 Quality Management

6.9. SOP-MAT-02 Receiving

6.10. SOP-MAT-03 Material Review - Nonconformance

7.0 FORMS AND RECORDS

7.1. Packaging List

7.2. Label Inventory List

7.3. Packaging/labeling Specifications

7.4. Manufacturing Batch Record

7.5. Label Issue Log

8.0 REVIEW FREQUENCY

8.1. Every two years.

9.0 DISTRIBUTION

9.1. Production Manager

9.2. Production Supervisors

9.3. Quality Assurance

9.4. Packaging and Labeling workers

9.5. SOP Library – worker access

10.0 REVISION HISTORY

Issue No.	Revision Summary	Effective Date
New	First Issue – New procedure	03.31.2017

11.0 DOCUMENT APPROVAL

	Originator:	Reviewed & Approved By:	Reviewed & Approved By:
Name			
Title			
Date			

Operations Plan(Inventory Management of Product)

D-6.1 By selecting "**Yes**" the Applicant attests that it will establish inventory controls and procedures for the conducting of weekly inventory reviews and annual comprehensive inventories of medical marijuana at the facility. OAC 3796:6-3-20

YES

D-6.2 By selecting "**Yes**" the Applicant attests that its written or electronic weekly and annual inventory records described in D-6.1 will include:

1. The date of the inventory
2. A summary of the inventory findings
3. The employee identification numbers, and titles or positions, of the individuals who conducted the inventory

Please reference OAC 3796:6-3-20 for more information.

YES

D-6.3 By selecting "**Yes**", the Applicant attests that it will use the state inventory tracking system. ORC 3796.07; OAC 3796:1-1-01; OAC 3796:6-3-06

YES

D-6.4 By selecting "**Yes**" the Applicant attests that it will maintain records of medical marijuana received from a cultivator or processor in its internal inventory control system. OAC 3796:6-3-20

YES

D-6.5 By selecting "**Yes**" the Applicant attests that it will maintain records of medical marijuana dispensed to a patient or a caregiver in its internal inventory control system. OAC 3796:6-3-08

YES

D-6.6 By selecting "**Yes**" the Applicant attests that it will maintain records of expired, damaged, deteriorated, misbranded, or adulterated medical marijuana awaiting return to a cultivator / processor or awaiting disposal, in its internal inventory control system. OAC 3796:6-3-20

YES

D-6.7 Please provide an explanation for selecting "**No**" in response to questions D-6.1 through D-6.6

n/a

D-6.8 Please describe the Applicant's approach regarding the implementation of an inventory management process. This approach must also include a process that provides for the recall of medical marijuana and the management of medical marijuana product returns from the proposed dispensary to the originating cultivator and/or processor. OAC 3796:6-3-20

A key employee will act as inventory manager and be the designated representative who has primary oversight of the dispensary's medical marijuana inventory control system, Metrc. Metrc will be real-time, web-based, backed-up at least daily and accessible by the state board of pharmacy immediately upon their request. In a power outage, a battery storage system shall be utilized and sized to provide uninterrupted electric power to key equipment during power outages for at least 4 hours. Metrc will

ensure that first in first out procedures are followed.
Metrc will document an exact accounting of:
*Each transaction and each day's beginning inventory, acquisitions, sales, disposal and ending inventory.
*Acquisitions of medical marijuana from a licensed processor or cultivator holding a plant-only processor designation, including:
-A description of the products including the quantity, strain, variety and batch number of each product received;
-For each finished product, the number of units or volume in each container and the number of containers;
*The name and license number of each of the processors and cultivators providing the medical marijuana
*The name and license number of the licensed processing and cultivating agents delivering the medical marijuana
*The name and license number of the licensed dispensary employee receiving the medical marijuana; the date of acquisition & any other
information the state board of pharmacy deems appropriate

All records of sales or dispensing of medical marijuana and denials of such sales will contain:
*A description of the products including the quantity, strain, variety and batch number of each product dispensed
*The name and license number of the licensed dispensary employee selling, dispensing, or denying the sale of medical marijuana
*the date of dispensing; and the name and registration number of the patient and, if applicable, the caregiver

Every disposal of medical marijuana will be documented electronically in Metrc according to the medical marijuana Waste Disposal Procedure:
*A description of the products, including quantity/weight, strain, variety, batch number and
*Cause for the medical marijuana being destroyed;
*The name and license number of the employee destroying the material;
*The name and license number of the dispensary key employee verifying the destruction of the medical marijuana or medical marijuana product;
*The method of disposal and the name, address and telephone number of the disposal company; and the date of disposal.

The State Board of Pharmacy will be notified at least 7 days prior to rendering medical marijuana unusable and disposing of it. Notification will include the date and time the marijuana will be rendered unusable and disposed.
The inventory manager will conduct daily inventory audits according to accepted accounting principles. If the audit identifies a reduction in the amount inventory not due to documented causes, the dispensary will determine where the loss occurred and immediately take and document corrective action. The dispensary will immediately inform the state board of pharmacy of the loss by telephone and provide written notice of the loss and the corrective action taken within two business days after first discovery. If the reduction in the amount of medical marijuana in the inventory is due to criminal activity or suspected criminal activity, the dispensary will immediately make a report identifying the circumstances surrounding reduction to the state board of pharmacy and law enforcement with jurisdiction where the suspected criminal acts occurred. If an audit identifies an increase in inventory not due to documented causes, the dispensary will determine where the increase occurred and take and document corrective action.
The dispensary will submit quarterly financial audit statements in a format and medium approved by

the state board of pharmacy. Quarterly audits may include, but are not limited to, an income statement, balance sheet and weekly medical marijuana inventory, including marijuana acquisition, wholesale cost and sales. An annual audit of the same information will be performed, certified and submitted by an auditor or certified public accountant. All audit results will be submitted in a format and medium approved by the state board of pharmacy.

The dispensary will maintain all inventory and financial records according to the record keeping procedures for three years from the date on the document. Digital records will be backed-up each day the dispensary is open for business. All records will be accessible and made available for review upon request.

In order to protect consumers from potentially adverse effects, a voluntary or mandatory recall of any product that is adulterated, or misbranded must be initiated immediately. The decision to voluntarily recall a product must be made by the key employee who has the authority to assign the recall classification to the situation in cooperation with the appropriate agencies. The Product Recall Team must be convened immediately when a Class I, II, or III situation exists and should include a key employee filling the following roles:

*Regulatory
*Production
*Sales
*Quality Control
*Public Relations
*Legal
*Purchasing

When a product complaint is received, the responsible key employee must be notified immediately. They will determine the necessary actions to follow. If a recall is deemed necessary, key employees will be convened to collect all information, determine the recall level, and plan the recall strategy according to the following classifications

*Class I – This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
*Class II – This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.
*Class III – This is a situation where the use of the product will not cause adverse health consequences.

Product complaints falling into Class I and Class II require that cultivator, processor, and the State Board of Pharmacy, department of Commerce and State Medical Board be notified upon discovery and classification. Class III recalls require that customers be notified. If a recall is deemed necessary, the product recall team will identify the location and quantities of all product shipped to all first-level recipients using shipping and sales records. This will include product shipped to distributors and directly to customers. The product recall team will determine how much, if any, of the product is still held in inventory, and how much was used as samples, damaged, spilled/lost, etc. During the recall process:

*A key employee must approve all information.
*All communication released regarding the recall must be released by a key employee. That individual will direct and approve all communications to distributors, retailers and consumers as appropriate and relevant via written notice, Attachment A. Notice may be communicated in conjunction with a public relations firm through email, postal delivery, company websites, social media, local newspapers, etc.
*A key employee or designee will be responsible for retrieving quantities, and date codes of all products shipped or sold from Metrc

A thorough investigation will be conducted until 100% of the product is accounted for. All product implicated in a recall that is returned will be identified as “Condemned for Destruction”, and will be placed in an identified “Quarantine” area of the restricted access area. When all condemned product has been assembled, the dispensary will destroy or return it to the supplier. After every reasonable

effort has been made to identify the locations of the product in question, and the product has been recalled/removed from the market, the recall is considered complete when the appropriate agencies, organizations and all customers have been notified in writing.

D-6.8.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-6.8. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final D-6.8.1 Recall Complaint Form, Recall Procedure SOP.pdf**
NOTE: This applicant uploaded document is the next 12 page(s) of this document.

Complaint Form

Date:		Complaint Report #:
Initiator:		Inspection Date:
Product:		Production Date:
Product Code:		Received Date:
Product Batch/Lot:	Quantity	Source/Supplier:

Complaint Information

Complaint Received By:	Date Received:
Customer:	Contact Name:
Contact Phone:	Contact Email:
Purchase Order #:	
Invoice #:	
Supervisor Assigned:	

Description of Complaint

Describe the complaint and attach supporting documents as needed.

Investigation

Product returned for investigation? Yes ☐ No ☐
Complaint confirmed? Yes ☐ No ☐
If Yes, explain and attach investigation notes (refer to CAPA if applicable):

Reportable Incidents

Does the complaint involve in patient injury or death? Yes☐ No☐
If Yes, explain:
Is the complaint reportable to regulatory authority? Yes☐ No☐
Is this issue first occurrence for the customer/vendor? Yes ☐ No ☐
If NO, list previous Complaint Report or CAPA number:

Support Documents

Final Response Communicated to Complainant? Yes ☐ No ☐
If no, justification:
CAPA issued? Yes ☐ No ☐ If yes, CAPA#:
If no, justification:

Approval Authorization

	Signature / Date
Initiator:	
QA Manager:	
Production Manager:	

TABLE OF CONTENTS

I. PURPOSE

A. To define the requirements and procedure for recalling a product that has been determined to be contaminated, adulterated, or misbranded and poses a threat to consumers.

B. To provide guidelines for the firm to test its ability to recall a product through mock recall exercises.

II. SCOPE

The requirements of this procedure apply to the recall of any product that has been determined to be, or is suspected of being contaminated, adulterated, or misbranded to prevent injury to consumers. This procedure also applies to any product produced using a raw material component, or product contact packaging component found to be contaminated, adulterated, or misbranded.

III. RESPONSIBILITIES

A. In order to protect consumers from potentially adverse effects, the affected licensee must immediately initiate a voluntary recall of any product that has been determined to be contaminated, adulterated, or misbranded.

B. The decision to voluntarily recall a product must be made by a responsible decision maker who has the authority to assign the recall classification to the situation in cooperation with state agencies. If a product deemed contaminated, adulterated, or misbranded is not recalled, the Ohio Board of Pharmacy may demand that the company do so.

C. The Product Recall Team must be convened immediately when a Class I, II, or III situation exists.

D. All information received in the process of recalling a product must be approved by the Product Recall Coordinator.

E. All communication released regarding a product recall must be released by the Spokesperson, if this person is someone other than the Product Recall Coordinator.

F. The Shipping Manager or designee will be responsible for recording quantities, and date codes of all products shipped from the warehouse, and the Shipping Manager or a designee will be responsible for maintaining these records as hard copies or on a computer file for a period not less than one year past the expiration date of the product.

G. Management must ensure that this procedure is reviewed annually.

IV. THE PRODUCT RECALL TEAM

The Product Recall Team should include persons with expertise in the following areas:

- Production
- Sales
- Quality Control
- Public Relations
- Legal
- Distribution

The Product Recall Team must be identified by responsibilities (coordinator and spokesperson at minimum), and 24-hour telephone contact numbers must be recorded. Members of the Product Recall Team are listed in Table 1 below.

Table 1 PRODUCT RECALL TEAM

CONTACT	Title	HOME PHONE NO.	OFFICE PHONE NO.	CELL PHONE NO.
	President			
	Director of Operations			
	Recall Coordinator			
	Spokesperson			
	Compliance Officer			
	Legal			
	Distribution Manager			

I. RECALL CLASSIFICATIONS

Class I – This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Class II – This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III – This is a situation where the use of the product will not cause adverse health consequences.

All recalls require that the Ohio Board of Pharmacy and customers be notified.

II. REQUIRED INFORMATION

A. The Recall Team must collect and document the following information regarding the product to be recalled:

- Product identity (description of the product being recalled)
- Lot number
- Quantity
- Reason for the recall (nature of defect)
- Level of distribution
- The recall classification
- The Ohio Board of Pharmacy contact
- List of customers to be contacted
- Applicable production and distribution records

VII. RECALL STRATEGY

A. When a product complaint is received, the Product Recall Coordinator must be notified immediately. The Product Recall Coordinator will determine the necessary actions to follow.

B. If a recall is deemed necessary, the Product Recall Team will be convened to collect all information, determine the recall level, and plan the recall strategy.

C. Using inventory, sales and shipping records, the Product Recall Team will identify the location and quantities of all product shipped to all first-level recipients. This will include product transferred to distributors, retailers and directly to consumers. If product has gone beyond the first level of distribution, the Product Recall Team will work in collaboration with distributors and retailers to identify and recall product distributed to all locations and consumers.

D. The spokesperson will direct and approve all communications to distributors, retailers and consumers as appropriate and relevant via written notice, Attachment A. Notice may be communicated in conjunction with a public relations firm through:

- Email
- Postal delivery
- Company websites

- Social media
- Local Newspapers, radio or television stations

E. Affected product will be retrieved by reversing existing distribution mechanisms. All first level recipients will be instructed to cease distribution, notify their customers of the recall and quarantine affected products until they can be returned to the company warehouse for quarantine and destruction pending closure of the recall. End consumers will be instructed to return any unused portions of affected products to the corporate office, distribution or retail outlets.

F. The Product Recall Team will determine how much, if any, of the product is still held in inventory, and how much was used as samples, damaged, spilled/lost, etc.

G. The investigation must be conducted until 100% of the product is accounted for.

H. All activities associated with the recall must be documented using the Product Recall Form, Attachment B.

I. Ohio Board of Pharmacy will be provided with weekly reports using the Product Recall Accountability Form, Attachment C, indicating the amount of affected product and the amount of affected product returned until such point that the has determined the risks to public health and safety are no longer present and the recall is closed.

VIII. DISPOSITION OF RECALLED PRODUCT

A. All product implicated in a recall that is identified in existing inventory or returned will be identified as “Condemned for Destruction”, and will be placed in an identified “Quarantine” area of the warehouse.

B. When all of the condemned product has been assembled, product destruction will be coordinated with and overseen by a local Ohio Board of Pharmacy enforcement officer using an approved method at the conclusion of the investigation.

IX. RECALL CLOSURE

After every reasonable effort has been made to identify the locations of affected products, and those products have been recalled/removed from the market, and the Ohio Board of Pharmacy has communicated in writing that the recall efforts are successful and risks to public health and safety are no longer present, the recall is considered complete.

X. MOCK RECALLS

A. The procedure described here for recalling a product must be tested on a scheduled basis to ensure its effectiveness, and the plant's ability to recall a product. Mock recalls to the first level of distribution should be conducted semi-annually, but at minimum annually.

B. Mock recalls to the first level of distribution should be completed in less than four hours with a recovery rate of 100% of all product implicated in the trace exercise. Any deviations should be explained clearly.

C. In addition to demonstrating the ability to recall an affected product, the company's ability to recall affected products based on potentially-defective raw materials, ingredients, or packaging materials that come in contact with the product should also be tested on a rotating basis.

D. Mock recall exercises should involve the members of the Product Recall Team who would be involved in an actual recall, as well as the alternate team members.

E. Documentation summaries should be prepared for each mock recall using the Product Recall Accountability Form, Attachment C. This should be an accounting of product produced vs. product shipped, product on hand and product documented as damaged, lost, samples, etc. The mock recall, results, and the required time to complete the exercise should be fully documented.

Attachment A:

URGENT: RECALL

Date:
Contact name or Department:
Firm name:
Address:
City/State/Zip:

Dear _____:
This is to inform you of a product recall involving:
< PRODUCT NAME, BRAND NAME, DESCRIPTION, UPC CODES, LOT NUMBERS>
See enclosed product label for ease in identifying the product at retail/user level.
This recall has been initiated due to <problem>. Use of <or consumption of> this product may <include any potential health hazard>.
We began shipping this product on <date> (or) This product was shipped to you on <date>. (If possible, provide consignee with shipping dates and quantities shipped.)

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter, or <Enclosed is a letter you should use in notifying your customers>.
[Notification must include instructions on what customers should do with the recalled product.]

This recall should be carried out to the <wholesale>, <retail>, <consumer>, <user> level.
Your assistance is appreciated and necessary to prevent <i.e. consumer illness or patient harm>.
Please complete and return the enclosed response form as soon as possible.
If you have any questions, call <name and telephone number>. This recall is being made with the knowledge of the Ohio Board of Pharmacy.

Name
Title

Enclosure(s)

Customer Acknowledgement Form

Description of items under recall: PRODUCT NAME, BRAND NAME, DESCRIPTION, UPC CODES, LOT NUMBERS

On behalf of this organization I acknowledge receipt of the Urgent Product Recall notice date [insert date of notice] relating to the above product(s).

Name		Date	
Position		Signature	
Organization			

Affected Stock

If you have no affected stock tick this box [ ]		
If you have affected stock please complete the table below		
Product	Batch/Lot/Date	Qty.
TOTAL AFFECTED PRODUCT		

Has affected product been distributed to any other organizations or consumers?

[ ] No
[ ] Yes (please supply names and contact information of the organizations or consumers)

Attachment B

PRODUCT RECALL FORM

Finished Product Lot No.	Customer	Location	Quantity of Product to be Recalled	Initials Verifying Notification of Customer

Attachment C

PRODUCT RECALL ACCOUNTABILITY FORM

Date of Recall:
Starting Time:
End Time:
Product Name:
Product Code:
Lot Number:
Raw Material Code:
Quantity of Raw Material Received:
Packaging Material Code:
Quantity of Packaging Material Received:
Total Wt. of Finished Product Produced:
Total Wt. of Finished Product in Inventory:
Total Wt. of Finished Product as Samples,
Lost, Spilled, etc.

Finished Product Shipped To:	Quantity
1.	
2.	
3.	
4.	
5.	

Total Weight Accounted For:
Percent Recovery:
Required Time:

Signature:

Date:

D-6.9 Please describe the Applicant's processes, procedures and controls regarding a patient or caregiver's ability to return unused medical marijuana for the purpose of dispossession and destroying. Include, at a minimum, a description of

1. How patients and caregivers will be charged for such returns
2. How returns will be tracked
3. How any returned medical marijuana will be secured at the facility
4. The maximum amount of time that returned medical marijuana will be stored at the facility

Products shall only be accepted for return due to an error in dispensing or recall. For each return the following information will be recorded in the inventory management system by voiding the sale and recording the following required information in the "reason for the void field."

1.The reason fro the return (dispensing error or recall)
2.The given name and surname of the client who returned the substance or on behalf of whom the substance was returned;
3.The address of the site at which it was received;
4.The name of the substance, its quantity and brand name; and
5.The date on which it was received.

If the product is returned due to a consumer complaint it must be documented and the appropriate key employee notified immediately upon receipt of the complaint. Written records must include, but are not limited to, the following:

1. Complaint number (for tracking purposes)
2. Name and description of product
3. Batch, lot, or control number
4. Complaint date
5. Manner in which the complaint was received
6. Complainant's name, address, telephone No.
7. Nature of complaint and how product was used (if applicable)
8. Findings of investigation and follow-up action
9. All correspondence associated with complaint
10. Initials
11. Dated reviewer's initials

Records of investigations involving complaints of possible hazard to health must be complete showing that all requirements for the investigation were met. These records must also show dates, times and the names of all individuals involved with the investigation. Complaints may be categorized by the appropriate key employee as one of the following:

Class I – This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Class II – This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III – This is a situation where the use of the product will not cause adverse health consequences.

Product complaints falling into Class I and Class II require that cultivator, processor, and the State Board of Pharmacy, State Medical Board and Department of Commerce be notified within 24 hours of discovery and classification. Class III recalls require that customers be notified. Every container of every product returned will be labeled with a tag that identifies the material as "Returned Product", "On Hold", "Quarantine", or other designation to show that the material is not available for use. Red tags will be used for this purpose and will contain the product name, product code, lot number, and the date the returned material was received. In addition to the identification tag, a corresponding permanent electronic log will be maintained that lists the date, the product name, product code, lot number, the quantity, number of containers, the reason for the return, results of any evaluation and the disposition of the material in question.

All returned products will be segregated in a designated, clearly identified area according to the appropriate product storage policy and procedure for returns. A computer block alone is not acceptable. If the reason for the return implicates associated batches, an investigation will be conducted of other suspect batches to determine compliance with specifications.

Only key employees will determine the disposition of a returned product. This authorization will be recorded in writing. On completion of the evaluation of a returned product by the disposition will be dated and signed. The disposition or corrective action will be commensurate with the seriousness of risk identified, and all non-conforming product will be handled or disposed of according to the destruction and disposal policy. Any returned product that does not meet specifications for identity, purity, quality, strength, and composition will be destroyed. Product destined for destruction must be adequately secured and disposed of within 30 days of the return and inventory updated appropriately. The State Board of Pharmacy will be notified at least 7 days prior to rendering medical marijuana unusable and disposing of it. Notification will include the date and time the marijuana will be rendered unusable and disposed. All medical marijuana or cannabinoid containing waste products will be disposed of by combining those elements with a mixture of paper, cardboard or other organic materials such as food or yard waste. The mixture makeup will be at least fifty one percent non-marijuana and will be ground to render it unusable. The material will then be stored in a secured and locked dumpster until collected by the waste removal company. Accurate inventory records will be maintained in the inventory management system showing the location, name and description, batch/lot ID and quantity/weight of material scheduled for destruction or disposal and the name of the key employee witnessing the destruction. All records pertaining to destruction will be maintained for a period of not less than 3 years. The inventory of withheld material will be reconciled at least weekly, and discrepancies investigated and properly documented.

D-6.9.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-6.9. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final D-6.9.1 Cannabis Waste Log, Waste Management SOP.pdf**
NOTE: This applicant uploaded document is the next 12 page(s) of this document.

Disposal Date	Disposed By	Witnessed By (or camera location)	Batch/Lot #

Cannabis Waste Log

Product Name / Strain	Quantity - Weight	Cannabis Waste Type Raw-Infused-Oil-Materials

Mixed With

1.0 SCOPE

1.1. Procedures to manage waste produced by cannabis production facilities.

2.0 OBJECTIVES

2.1. Provide procedures to develop and maintain a waste management plan that ensures all waste generated during production is reused, recycled and disposed of according to regulations and company policies and procedures.

2.2. Limit the impact of production waste on the environment by reducing the amount of waste generated, processing all waste appropriately, reducing landfill waste volume and supporting the operation's conservation plan.

3.0 RESPONSIBILITIES

3.1. Management sets the conservation policy, authorizes appropriate procedures and holds staff accountable.

3.2. Operations/Production Manager implements procedures and maintains the appropriate support mechanisms and trained staff to support the waste management policy.

3.3. All workers are responsible for following procedures and reporting any waste management violations to the Operations Manager.

4.0 DEFINITIONS AND ABBREVIATIONS

4.1. Cannabis Waste Any raw cannabis, cannabis-derived or cannabis-containing product produced, procured or stored by the operation that is deemed unusable and designated for disposal.

4.2. Cannabis Materials Any material or by-product that contains cannabis or cannabis-derived materials.

4.3. Waste Management Plan Policies and procedures to control pollution, meet environmental regulations and goals, and safely handle, reduce, store and dispose of waste and recyclables.

5.0 PROCEDURE

5.1. Waste Management Policies

5.1.1. Management ensures all waste produced by any part of the operation is managed and disposed in a safe, compliant and responsible manner.

5.1.2. Management develops a Waste Management Plan, ensures all workers understand and follow the associated procedures, and reviews and updates the Plan annually.

5.1.3. Management assesses all waste management risks and documents risks and mitigations in the operation's Waste Management Plan.

5.2. Waste Management Methods

5.2.1. The operation's waste management procedures ensure waste storage and disposal does not promote or harbor pests, filth or other contaminants that might contaminate products, materials or equipment.

5.2.2. Grounds and facilities are properly maintained through removal of litter and waste, cutting of grass and weeds adjacent to buildings, maintenance of roads and parking lots, providing adequate drainage, etc.

5.2.3. Sewage and waste disposal is properly plumbed from the facility and does not provide a potential source of contamination to contact surfaces, products, components, water supplies, etc.

5.2.4. Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.).

5.2.5. Backflow and cross-connection prevention is in place.

5.2.6. The Operations Manager reviews and records all deviations to waste management procedures.

5.3. Waste Management Plan

5.3.1. The operation's Waste Management Plan defines the policies and procedures to control pollution and safely handle, reduce, store and dispose of waste and recyclables for each separate location. The Waste Management Plan:

a. Specifies who is responsible for managing waste at each location.
b. Establishes goals and objectives for waste management.
c. Identifies the types of waste produced and the estimated amounts to be produced.
d. Documents risks, preventative action and mitigation plans.
e. Sets targets for reducing the amount of each waste type.
f. Documents the recycling/reuse/disposal methods for each waste type.

g. Defines the products that are safe for disposal through standard waste management methods.

h. Defines measures for specially designated material use, handling and transporting:

- Cannabis and products containing cannabis
- Hazardous materials, solvents, flammables
- Contaminated equipment (pipes, soil, etc.)

i. Identifies the waste destinations and transport modes, including what materials are segregated on site for reuse or recycling.

j. Sets procedures to ensure all waste materials and effluent are disposed of in accordance with current local regulations.

k. Identifies approved transportation routes appropriate for the class of material transported.

l. Provides requirements to track waste management activity and progress including volume produced, volume disposed, recycling/reuse results, waste reduction metrics, solutions, nonconformity and corrective action.

m. Defines communication and training required for workers to understand and properly conduct responsibilities.

5.4. Cannabis and Cannabis Infused Waste

5.4.1. The operation segregates all cannabis waste (raw and infused product, cannabis materials) for special processing.

5.4.2. Authorized workers render cannabis and cannabis-infused product waste unusable and unrecognizable prior to leaving the facility.

5.4.3. Prior to processing, an authorized worker weighs the cannabis waste (weight, plant ID, lot number) and records it in the inventory system.

5.4.4. The worker is observed by a camera or another authorized worker during the mixing and disposal process.

5.4.5. Workers incorporate non-consumable, solid wastes into the cannabis waste so that the resulting mixture is at least 50 percent non-cannabis waste.

5.4.6. No waste is discarded that is recognizable as raw cannabis or cannabis leaves, flowers or other usable cannabis form.

5.4.7. Depending on availability and related processes, the operation uses one or more of the following substances to render cannabis waste unusable and unrecognizable:

a. Soil or soil mix
b. Paper waste
c. Cardboard waste
d. Food waste
e. Compost activators

5.4.8. Workers ensure any cannabis waste containing flammable solvents is dried safely and processed according to the waste management plan.

5.4.9. Other waste processing methods are acceptable if justified and documented.

5.5. Hazardous Materials Disposal

5.5.1. The operation documents and maintains an accurate inventory of all hazardous materials used in the operation.

5.5.2. Hazardous materials include cannabis, cannabis product waste, solvents, chemicals, agricultural inputs and cleaning agents.

5.5.3. The operation disposes of chemical, dangerous or hazardous waste in compliance with applicable regulations.

5.5.4. Workers update the Hazardous Material Log when processing any hazardous waste.

5.5.5. Workers receive training on hazardous material handling, spill cleanup and recordkeeping as part of ongoing health and safety training.

5.6. Waste Management Permits

5.6.1. The Operations Manager consults with local and state agencies to verify waste management permit requirements based on each operation's location.

a. Environmental permit
b. Waste transportation permit
c. Landfill authorization
d. Waste storage permit
e. Operations Manager secures required permits
f. Files and posts as required

g. Adds permit renewal deadlines to task calendar

5.7. Use of Waste Management Contractors

5.7.1. When used, the operation ensures third-party waste management contractors possess valid, appropriate permits, licenses and insurance to transport and process the operation's waste in compliance with all regulations.

5.7.2. Contractors are qualified and managed through the supplier qualification process and performance is reviewed annually.

5.8. Waste Container Control

5.8.1. All internal and external areas where waste collection containers are located are maintained and clean with no visible debris, spills or containers.

5.8.2. If required by security procedures, external waste containers are locked.

5.8.3. Waste is removed from all of the operations trash containers at least daily and disposed of in the authorized waste container.

5.8.4. Waste containers are not permitted to be overfilled.

5.8.4.1.1. If overfilling occurs, Operations Manager contacts the waste management provider for special pick up or processes the waste onsite resolve overflow.

5.8.5. All containers, dumpsters, etc., are equipped with easily closable lids.

5.8.6. Lids are lockable as required by the Security Plan.

5.9. Records Management

5.9.1. The operation ensures waste management actions, issues and corrective action reports are documented and shared with appropriate managers and staff.

5.9.2. All waste management records are retained for at least two years; any records subject to alternate regulatory retention requirements are retained accordingly.

5.9.3. Records are managed and tracked according to records management procedures.

6.0 REFERENCES

6.1. ISO 9001:2008 Quality Management Systems Requirements

6.2. SOP-FAC-02 Facility Management

6.3. SOP-MAT-01 Supplier Qualification

6.4. SOP-MGT-02 Risk Management

6.5. SOP-MGT-03 Records Management

6.6. SOP-SAF-01 Health and Safety

7.0 FORMS AND RECORDS

7.1. Conservation Plan

7.2. Hazardous Materials Log

7.3. Waste Management Plan

8.0 REVIEW FREQUENCY

8.1. Every two years

9.0 DISTRIBUTION

9.1. Managers and Supervisors

9.2. Facilities Department

9.3. SOP Library worker access

10.0 REVISION HISTORY

Issue No.	Revision Summary	Effective Date
New	First Issue – New procedure	03.31.2017

11.0 DOCUMENT APPROVAL

	Originator:	Reviewed & Approved By:	Reviewed & Approved By:
Name			
Title			
Date			

Operations Plan(Diversion Prevention of Product)

D-7.1 Please provide a summary of the procedures and controls that the Applicant will implement at the dispensary for the prevention of the unlawful diversion of medical marijuana, along with the process that will be followed when evidence of theft/diversion is identified. OAC 3796:6-3-01; OAC 3796:6-3-05; OAC 3796:6-3-16

[redacted]

Operations Plan(Sanitation and Safety)

D-8.1 Please provide a summary of the intended sanitation and safety measures to be implemented at the dispensary. These measures should include, but are not limited to, plans, procedures, and controls to address the following:

1. Processes for contamination prevention
2. Pest protection procedures
3. Instruction to dispensary employees regarding the handling of medical marijuana
4. Hand-washing facilities

Please reference OAC 3796:6-3-02 for more information.

Preventing direct and secondary contamination is a complex process that requires appropriate and robust facility design, facility/equipment sanitation and maintenance, pest management, personnel practices, and training to support employees in compliance with those activities.

Facilities will be designed with smooth, easily cleanable surfaces and include adequate and conveniently-located hand washing sinks in locker rooms, cafeteria/break rooms, toilet facilities and at entrances to work areas. Toilet and locker facilities will be in an area separate from or far enough away so as not to pose a risk to product. Doors will be self closing and not open directly into any area where product is exposed or stored.

The number of hand washing stations will be adequate to accommodate the number of employees in each area. All handwashing stations will have hands-free controls so that hand contact is not required to turn water on or off, signage to remind workers to wash hands be equipped with hand sanitizing soap and/or sanitizing agent, single-service towels or a blow dryer, and a conveniently located, approved waste disposal container and deliver water at a temperature of 90-105 degrees within 10 seconds.
Facility and equipment sanitation will be supported through the implementation of a Master Sanitation Schedule, written sanitation and cleaning procedures as well as documented training on those elements.

Procedures and training will at a minimum cover the following:
• Worker responsible for cleaning
• Item/area to be cleaned
• Specific cleaning methods
• Tools, utensils and cleaning products used
• Frequency of cleaning
• Water temperature requirements, where applicable
• Safety, PPE and chemical controls:
o Dilution and mix hazards
o Application procedures
o Labeling, containers and storage
o Personal protective equipment
o Spill clean up
o First aid
• Accurate and current sanitation logs that cover all areas of the facility and all equipment to identify:
o What was cleaned
o Who cleaned it
o When it was cleaned

Prior to initiating cleaning or sanitizing activities, raw materials, work-in-process, finished goods and

packaging materials will be removed from the area. "Cleaning" includes sanitizing equipment surfaces and general cleaning of fixtures, floors, walls tables, doors, etc., in the work area. To support effective cleaning and sanitizing procedures periodic environmental testing (swab testing, air impaction or equivalent methods) will be performed. Documented test results will be maintained. In the event cleaning or sanitizing activities are found to be ineffective all corrective and preventative actions will be documented.

With effective pest management, the entire facility should be free of pest contaminants such as whole or parts of insects, rodents, birds, reptiles or mammals, feces, hair and other pest waste to the maximum extent practical. Documented inspections of the following will be performed to identify any evidence of pests or pest debris on a monthly basis at a minimum:

• Product
• Packaging
• Storage areas
• Equipment, equipment accessories and utensils
• Office or non-production support areas
• Dining and break areas
• External areas except for normally occurring pest debris (i.e., insects concentrated around light fixtures and natural bird and insect activity).

Pest Management will be accomplished through implementation of a documented pest management plan developed by a certified pest control operator. The purpose of the plan is to protect products, storage areas, packaging, equipment and supplies from pests and disease, discourage pest populations and prevent disease. The plan will incorporate product safety and quality controls to minimize risks to products, people and the environment. Documentation will include:

• Dates of service
• Records of pest activity
• Dates discovered and remedies pursued
• Chemical used
• Code number
• Target pest,
• Locations where used
• Date used
• Concentration
• Total quantity used, and
• Method of application at minimum

Pest control devices (traps, light traps, etc.) placed to prevent contamination will be maintained in working order, marked, numbered and coded for regular inspections.
Employees involved in handling medical marijuana will receive training on personal hygiene practices. This training will include basic knowledge of microbiological organisms that could contaminate products - what they are and how they can contaminate products. The training program will stress the employee’s responsibility to protect product quality and product safety by following proper hygienic practices. Hygienic practice policies will at a minimum require the following elements:

Outer garments

• Employees who handle exposed products, product-contact components, or equipment will be required to wear company-issued smocks or lab coats.

• Outer garments must be maintained clean at all times
• Smocks or lab coats shall not be worn in toilet areas or in employee cafeteria/break rooms.
• Outer garments may not be taken home to be laundered.
• Employees who handle microbiologically-sensitive products must wear shoe covers when handling such products
• All maintenance employees, visitor and contractors must comply with the policy.

Hand Washing

• All employees must wash their hands thoroughly using single-use liquid soap and hot water before starting work, after breaks, after using rest rooms, or whenever hands become contaminated.
• The use of an approved hand sanitizer is allowed, however, the use of hand sanitizers cannot be a substitute for effective hand washing.
• Visitors and contractors will be required to observe the hand sanitation policy.

Gloves

• All employees who handle raw materials, in-process materials or product-contact surfaces, will wear sanitary gloves approved for food contact use.
• Fabric glove liners may be worn under sanitary disposable gloves.
• Gloves must always be intact and kept clean, and they must be replaced whenever they become damaged or contaminated.
• Visitors and contractors must also comply with the glove policy.

Jewelry

• Employees coming into contact with exposed product will not be permitted to wear jewelry such as chains, bracelets, watches, rings, etc. The policy will also forbid the wearing of facial adornment such as appliqués, stones, exposed body piercings, false fingernails, or fingernail polish.
• Plain wedding bands may be worn, provided they are covered with an approved sanitary glove. Rings with stones must never be permitted.
• All visitors and contractors will be required to comply with the jewelry policy.

Hair Restraints

• Employees coming into contact with exposed product must wear fine-mesh hairnets.
• Hairnets must be properly sized and worn over the ears in a manner that covers all hair. If necessary, two hairnets may be worn.
• Except for neatly-trimmed mustaches that do not fall below the lip line, all mustaches and beards must be covered with a beard/mustache cover.
• All visitors and contractors to the plant must comply with the hair restraint policy.

Personal Effects

• Personal items such as coats, pocketbooks, bags, lunch boxes, food/drink items, etc. are not permitted in any areas where exposed product is present.
• Food or drinks must not be stored in personal lockers.
• Management will conduct routine, documented inspections of personal lockers.

Consumption of Food and Other Items
• No medical marijuana or medical marijuana products shall be consumed on the premises

• Patients and caregivers will only be allowed to consume complimentary non-alcoholic beverages provided by the dispensary on the premises
• Food and drinks must be consumed only in designated areas
• The policy also forbids use of items such as: cosmetics and skin preparations, throat lozenges, and medicines in areas where products are exposed or stored.

Operations Plan(Record-Keeping)

D-9.1 By selecting "Yes," the Applicant attests that it will notify State Board of Pharmacy at least 7 days prior to rendering medical marijuana unusable. All waste and unusable product will be weighed, recorded and entered into both its internal inventory system and in the state inventory tracking system. The destruction of medical marijuana will be witnessed by a key employee and conducted in a designated area with fully functioning video surveillance. OAC 3796:6-3-14

YES

D-9.2 Please provide a summary of the Applicant's record-keeping plan at the dispensary. This plan should cover, but is not limited to, a description for how the following records will be maintained:

1. Employee records, including a background check conducted by the proposed dispensary and training provided by the proposed dispensary
2. Operating procedures and controls
3. Audit records
4. Staffing plans; Business records
5. Surveillance records
6. Attendance logs
7. Quality assurance review logs

Please reference OAC 3796:6-3-17 for more information.

Ohio Valley Wellness, LLC will be using PowerDMS Software System as our program to detail the document storage location and retention of each vital records. PowerDMS is a software platform that supports management of policies, procedures, training and accreditation. Law enforcement, fire, and federal aviation agencies utilize PowerDMS as their online document management, retention, and compliance system. Access to PowerDMS is provided through our Certification Contract with Foundation of Cannabis Unified Standards (FOCUS) – the Cannabis Health and Safety organization. PowerDMS will be used to detail the storage location and retention of each of the vital records. PowerDMS allows immediate access to any records as part of an investigation or as part of a data-driven process improvement venture. PowerDMS will be assigned to an employee with appropriate time allotment, skills and experience will be assigned to manage the PowerDMS system. Ohio Valley Wellness, LLC management team will conduct a self-assessment of the records process at least every 90 days. Additionally, as part of our annual certification with FOCUS, a third-party, independent auditor will do both a digital and onsite assessment on an annual basis. Each assessment will be documented, including the completion of any corrective actions.

PowerDMS will ensure the organized storage, retention and protection of all records and supporting data, including:
• Records Inventory List – A master list of records and control requirements including:
o Employee Records
o Business Records and Staffing Plans
o Surveillance Records
o Operating Procedures
o Audit Records
o Quality Assurance Records
o Attendance Logs
• Record Retention – Retention time and destruction/deletion methods

All digital files will be managed according to procedures including:
• System access controls

• User controls and tracking (viewing, printing, editing and deleting)
• Standard file labeling and organized storage hierarchy
• Data encryption
• File deletion schedules and processes including deletion of data on obsolete computers and data storage devices
• Data backup: cloud storage, digital storage service, offsite storage of backup hard drives
• Automatic file backup
• Long-term protection and file integrity

All physical files will be stored according to procedures including:
• Restricted storage areas
• Lockable filing systems
• Sign in/sign out procedures for file review/removal
• Organized filing systems
• Physical records are filed in a timely manner
• Destruction schedules and processes
• Crisis protection
• Long-term storage/environmental controls

Record Inventory List:

All documents included in the record inventory list will be maintained electronically in the PowerDMS and Seed to Sale tracking software. PowerDMS will be used to support the management of all policies, procedures, training, assessments, and accreditation.

The Records Inventory List will identify:
• Each record by title
• Persons/positions authorized to view the record
• Revision or deletion authorizations and activities
• Retention period
• Destruction method
• Storage and back-up requirements
• Record location (if electronic, file path and filename)
• Other controls as required

The Records Inventory List will also identify all records related to the following categories (there may be multiple records per category):
• Accounting ledgers and reports
• Tax returns, tax correspondence and supporting information
• Payroll and wages
• Contracts and agreements
• Corporate organization, bylaws, organization charts, business and staffing plans
• Insurance
• Intellectual property
• Legal files, court documents, attorney files
• Public filings
• Security records
• Logins and electronic permissions
• Electronic mail
• Employment and worker files
• Training records and program documentation

• Safety and health (OSHA, worker's comp, medical, SDS)
• Audit reports, inspection reports and self-assessments
• Quality control procedures, logs and records
• Approved 3rd party vendor list
o List of items approved for acquisition
o Contact person
o Contact information
• Vendor records
o Order history
• Vendor records
• Customer information
• Patient/customer records
• Inventory records
• Product test data and test lab reports
• Product transfers
• Test method documentation (lab only)
• Sample management and control records
• Sales and marketing plans
• Sales transactions
• Press releases
• Maintenance logs for facilities and equipment
• Calibration, maintenance and repair logs
• Sanitation logs

Record Retention:

All records will be maintained under secure, controlled conditions for a period of not less than three years. Records that have reached or exceeded their retention period may be destroyed by any means that renders them illegible, such as shredding, incineration, or sent to an approved landfill. Destruction of records will be ordered by an authorized individual who must sign a destruction notice. Destruction notices must also be signed by the person who destroys the records as evidence of the destruction. Record of all records that are destroyed will be maintained, indicating the types of records destroyed, the period of time the records covered, the method of destruction, date of destruction, initials of the person who authorized the destruction, and initial of the person who destroyed the records.

Operations Plan(Other)

D-10.1 Please provide a summary of any other services or products to be offered by the Applicant at the dispensary. OAC 3796:6-2-02

Ohio Valley Wellness, LLC will not only be a dispensary but also a medical wellness center. Our goal is to understand the patient's specific needs and be involved in their well-being by asking the appropriate medically related questions. This will allow us to deliver the best patient-specific product and services to each patient while aligning with the standards of practice according to the Ohio Board of Pharmacy. We will strive to be the face of wellness and partner with medical clinics to develop close working relationships with clinicians as well as patients. Patient profiles will be updated to monitor and ensure minimization of potential adverse events due to drug interactions.

As a part of the initial patient intake process and in support of continuity of care, all patients will be offered and encouraged to participate in in-depth medication management counseling by a team of licensed pharmacists and physicians. These counseling sessions will be conducted in the comfort of our patient/caregiver education and consultation room. Independent of accepting medication management counseling, all patients will be provided with documentation developed by the medical team that includes the following categories as apart of both the education and service offerings:
• Effectiveness of strains of medical marijuana for specific conditions based on available scientific literature and anecdotal reports from patients.
• Information on the properties of the cannabinoids and terpenes in selecting products for use
• Basic principles of Absorption, Distribution Metabolism and Excretion (ADME) to help patients better understand the time-effect relationship between consumption and therapeutic effect
• How medical marijuana interacts with the endocannabinoid system
• Methods and forms of consumption or inhalation via vaping of medical marijuana (with reiteration on prohibiting smoking or combustion of medical marijuana)
• Signs and symptoms of possible side effects as well as contraindications
• Information regarding signs and symptoms of substance abuse, tolerance, dependency, and withdrawal
• Resources for patients in need of assistance dealing with dependency, abuse, or withdrawal
• Possible impairment with use and operation of a motor vehicle or heavy machinery and tending to children and other individuals
• Risks associated with marijuana use for pregnant and lactating women
Additional topics that may be covered during patient education offerings include classes on approved conditions such as: Aids, ALS, Alzheimers, cancer, chronic encephalopathy, Crohn's disease, epilepsy, fibromyalgia, glaucoma, hepatitis C, IBD, MS, chronic/severe pain, Parkinson's, HIV, PTSD, sickle cell, spinal cord injury, Tourette's, Traumatic brain, UC.

The dispensary will also make available information about possession and use of medical marijuana to patients and caregivers. Including limitations on the right to possess and use medical marijuana. All information will be submitted to the board prior to being shared with qualifying patients and caregivers.

The Products offered by Ohio Valley Wellness, LLC will largely be determined by availability in the marketplace. The goal is to offer a selection of products that are representative of the approved routes of administration and allows options for patients with complex health conditions that may not respond to a certain dosage form:
Flower material
Vape Pens/E-cigarette devices
Vaporizers
Oral

Infused edible products
Lozenges
Capsules
Sublingual dissolving tablets
Dermal
Lotions
Creams
Transdermal patches

Offering a selection of vaporizers or other delivery devices to patients for purchase creates an opportunity to educate patients on how to use the device to achieve full therapeutic benefit. Doing so also provides a mechanism for individuals who may not be comfortable visiting other non-wellness focused facilities, to feel comfortable and have confidence their questions will be answered correctly by a trained medical professional.

D-10.1.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-10.1. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Letter of Rec from City Planner.pdf**
NOTE: This applicant uploaded document is the next 1 page(s) of this document.

City Of
EAST LIVERPOOL
DEPARTMENT OF PLANNING AND DEVELOPMENT
CITY BUILDING OHIO, U.S.A. 43920
126 WEST SIXTH STREET
330-385-5394

November 14, 2017

To whom it may concern,

I believe that establishing a medical marijuana dispensary in our community would expand options for patients in our community and across the state to utilize medical marijuana for management of medical afflictions as an alternative to more dangerous addictive prescription medications.

As a proponent of medical marijuana as an option for our community members, I support this application to establish a medical marijuana dispensary license to Ohio Valley Wellness LLC. The dispensary has the potential to add important benefits to our community including health options, revenue to our city, and employment opportunities all for the betterment of our community.

I highly recommend this business, Ohio Valley Wellness LLC, and support this endeavor to help lead the community to more aligned wellness.

Sincerely,

William L. Cowan
Director of Planning

D-10.2 Please provide a summary of intended services for veterans and/or the indigent. OAC 3796:6-2-02; OAC 3796:6-3-22

Who Qualifies:
• Veterans
• Low-income patients

Discount Amount:
• 15% off
To Qualify:
• Must have current Ohio Medical Marijuana Patient License AND
• Must be a Military Veteran (with proof of status – VA/Military ID card or DD214) OR
• Must prove indigent status, determined by the board during patient registration

To Enroll:
• Must submit completed application for all applicants AND
• Must provide board documentation of indigent status OR
• Must provide VA/Military ID card or DD214

Persons in Family/Household Income Limit
1 $ 22,500
2 $ 31,000
3 $ 39,500
4 $ 47,000
5 $ 55,500
6 $ 65,000
7 $ 73,000
8 $ 82,500

Program Approval:
• Application for approval doesn't automatically mean they qualify.
o Applications will be reviewed by the dispensary manager as well as a dispensary key employee. Once it is deemed the patient has submitted all necessary paperwork and meets the qualifying standards, they are notified via mail, email, or telephone and their electronic patient file is noted. Their submitted paperwork will also be uploaded into their electronic patient file.
• Participants must provide updated income documents annually.
• Approval and/or continued participation is at the sole discretion of the dispensary manager.
• A dispensary key employee will Audit this program once per month to confirm all records are up to date and which patients need to renew their paperwork.
• Dispensary key employees will update this program as needed to assist in helping indigent and veteran patients.

D-10.3 Describe the Applicant's efforts to minimize the environmental impact of the proposed dispensary. OAC 3796:6-2-02

Ohio Valley Wellness, LLC is committed to promoting environmental sustainability. Both our business strategy and our corporate practices are designed to align with environmental regulations and best practices. Furthermore, our corporate perspective views the environment as a resource not only for us but for future generations. As such, we believe our role is to minimize our impact on the environment and promote sustainable behaviors.

Ohio Valley Wellness, LLC will have a minimal environmental impact on the community and on public and private property. It is our intention to utilize all applicable LEED (Leadership in Energy and Environmental Design) green building technologies and operating strategies.

1. Structure
a. The 3,200-square foot structure will be built/modified to minimize both ambient heat gain and heat loss through the installation of high R-value wall and roof insulation.
b. The structure will utilize low-transfer, multi-paned window glazing.
c. The penetrations in the structure will be sealed against infiltration with flexible seals and non-hardening sealants

2. HVAC Systems
a. The HVAC systems will be designed to provide the necessary sensible and latent cooling to maintain critical product storage conditions.
b. The system will introduce sufficient fresh air to dilute both CO_2 and VOCs present via a modulating intake damper and powered exhaust.
c. The volume of makeup air will be controlled via both VOC and CO_2 monitoring devices and modulating controls.
d. The system will include an ambient air/exhaust sensible air heat exchanger to temper makeup air, with an anticipated 55% efficiency.
e. The system will utilize a heat-pump cycle, along with supplemental natural gas hot water heating, to maintain a minimum of 65 degrees F wintertime temperature.
f. The outdoor heat exchange surfaces will be fitted with evaporative pre-cooling to maintain a maximum of 85 degrees F entering air temperature.
g. Air distribution will be via insulated ductwork with an R-11 rating.
h. Building space temperature will be controlled by programmable, set-back thermostats.
i. Air conditioning condensate will be carried to a drywall adjacent to the structure.

3. Life Safety
a. The facility will be equipped with appropriate smoke detectors, horn-strobe alarm lights and pull stations.
b. The facility will be equipped with a central annunciator panel with rechargeable battery backup.
c. All exit paths will be illuminated by emergency light/exit signs per local architectural requirements.
d. The facility will be equipped with the required Type ABC fire extinguishers.

4. LED Lighting
a. External security lighting will be via high-intensity LED fixtures controlled by a photoelectric sensor with a timed over-ride.
b. Internal space and task lighting will be via dimmable LED fixtures.

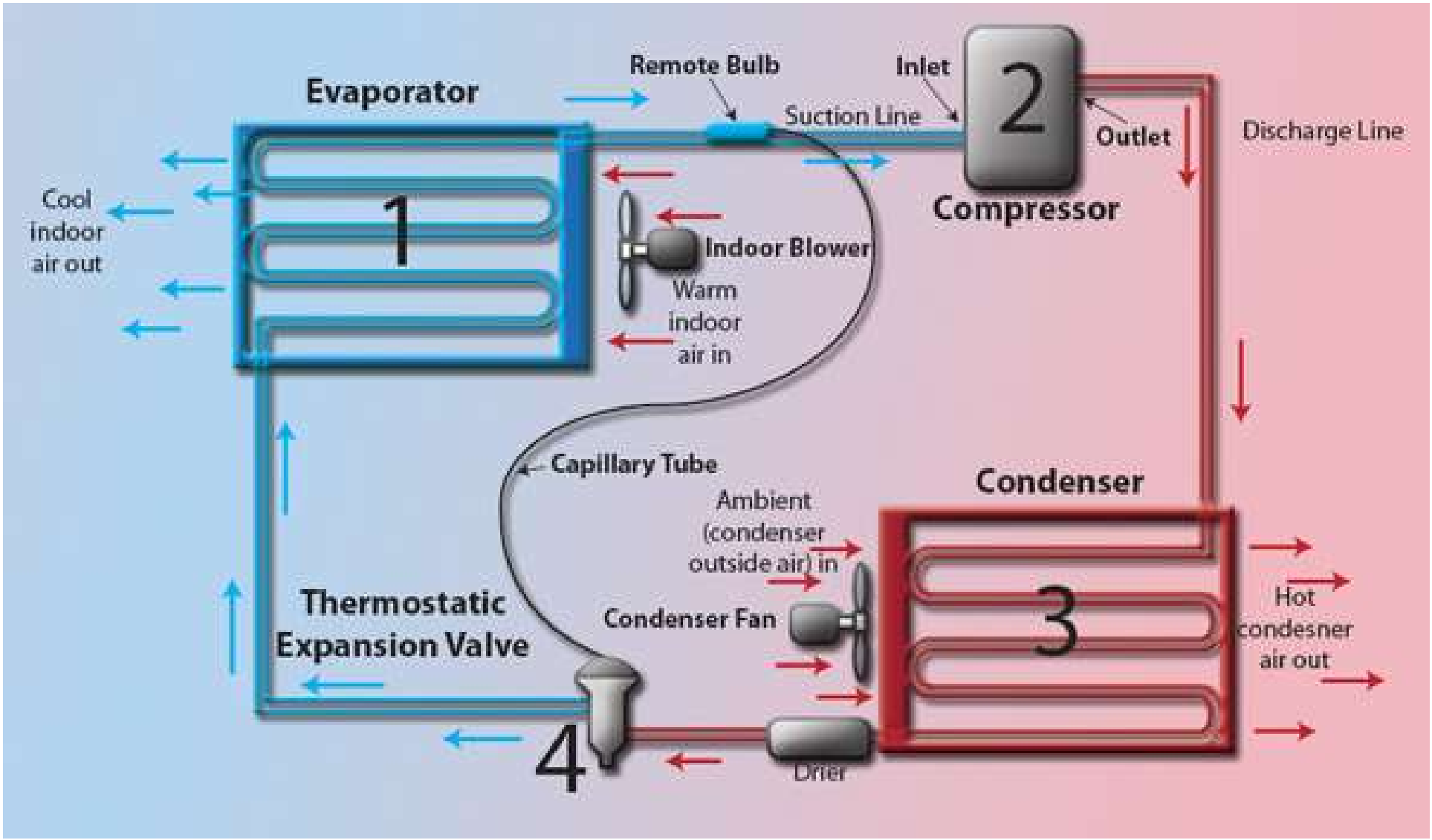
5. Site ADA Compliance
a. The site will be provided with the required number of parking spaces to accommodate personnel and public activity.
b. The appropriate number of van-accessible, ADA-compliant parking spaces will be provided adjacent to the building entrance.
c. The site will be provided with an appropriately-pitched, ADA-compliant wheelchair ramp.
d. ADA-compliant bathrooms will be included in the installation.
e. Doors will be equipped with suitable ADA-compliant, lever-type hardware.

6. Hazardous Exposure Limits
a. No known hazardous chemicals, solvents, gases or powders will be inventoried on site.

b. No manufacturing or assembling of any hazardous compounding will take place on site.
c. No hazardous chemicals will be introduced into the building sewer connection

D-10.3.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in D-10.3. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final D-10.3.1 HVAC, Smart Thermostat, Building Energy Quotient.pdf**
NOTE: This applicant uploaded document is the next 4 page(s) of this document.


Evaporator
Remote Bulb
Inlet
2
Suction Line
Outlet
Discharge Line
Cool
indoor
air out
1
Compressor
Indoor Blower
Warm
indoor
air in
Capillary Tube
Condenser
Ambient
(condenser
outside air) in
Thermostatic
Expansion Valve
Condenser Fan
3
Hot
condesner
air out
4
Drier


weather
indoor humidity
alerts
HELP
temperature settings
current temp
75
cool to
74
program is OFF
system is cooling
system settings
heat & cool
cool only
heat only
off
emerg. heat
select
fan setting
auto
on
circulate
select
indoor settings
programs
zones
HOME
May 21, 2013

Building Energy Quotient

ASHRAE's Building Energy Labeling Program

Worksheet Updated 3/1/2015

FORM 1 - BUILDING CHARACTERISTICS FOR IN OPERATION RATING

Building Name:				**Assessment Date:**	
Address:					
City:		State/Prov:		Zip/Post:	
Building Owner:		**Building Type:**			
Building Contact/Title:				Phone:	
Address:				E-mail:	
City:		State/Prov:		Zip/Post:	
Assessor Name/Company:				Phone:	
Address:				E-mail:	
City:		State/Prov:		Zip/Post:	

Climate Data

DOE Climate Zone:		HDD65:		CDD50:		Period of Data:	
Source of Climate Data:							

Building Characteristics

Gross Floor Area (ft^2):		Gross Conditioned Floor Area (ft^2):			
Separately Metered EXCLUDED Area (ft^2):		**Net RATED Floor Area (ft^2):**		0	
Number of Conditioned Floors:		Floors Above Grade:		Floors Below Grade:	
Original Year of Construction:		Hours of Operation:			

Brief Building Description (construction and use):

Description of On-Site Renewable Energy Systems (include rated thermal or electrical capacity):

Description of Major Renovations including years completed (List top 3, use Additional Notes Sheet for others):

1	Year:	
2	Year:	
3	Year:	

Building Systems Commissioned including years completed (List top 3, use Additional Notes Sheet for others):

1	Year:	
2	Year:	
3	Year:	

Energy Efficiency Improvements since Construction including years completed (List top 3, use Additional Notes Sheet for others):

1	Year:	
2	Year:	
3	Year:	

Other Operational Features (List top 3, use Additional Notes Sheet for others):

1	Year:	
2	Year:	
3	Year:	

Brief List of Building Photos Included with submission (Insert Photos into separate worksheet tab marked Photographs):

Building Performance Credentials

ENERGY STAR Score:		Years:		☐ GreenGlobes Rating:		Years:	
LEED Rating/Version:				LEED EA Points:			
Other Rating (select):				Version/Score (enter):			
Other Rating (select):				Version/Score (enter):			

Building Energy Quotient

ASHRAE's Building Energy Labeling Program

Worksheet Updated 3/1/2015

Designed to meet ASHRAE Advance Energy Design Guide	Specify:	
Designed to meet state/provincial/international energy code:	Specify:	

Operations Plan(Security & Infrastructure Records)

D-11.1 By selecting "Yes", the Applicant attests that all responses identified as containing security and infrastructure are voluntarily submitted to the State Board of Pharmacy in expectation of a protection from disclosure as provided by section 149.433 of the Revised Code.

YES

Patient Care(Staff Education and Training)

E-1.1 Describe the Applicant's education and training plan and how it will meet the foundational and ongoing training required for dispensary employees to be authorized to dispense medical marijuana. Include a summary of the substantive training content, the number of hours each dispensary employee will receive for each mandatory training requirement, the number of training hours each dispensary employee will receive for any elective training, and the anticipated source of each type of training described. OAC 3796:6-3-19

The Dispensary will have a designated employee position for all Employee On-boarding and Training. This position will handle all employee training from the day they are hired and their continuing education.

Each time an employee completes any initial continuing education training an individual Training Completion Form will be filled out and stored in PowerDMS as a digital record and also stored as paper file. The Training Completion Form will include: the participant's name, course title, course content, date(s) of training, providers name(s), and signature of the course instructor.

All employees will receive step by step, relevant, comprehensive training on how to use the OARRS and METRC system with the ASAP 4.2A format.

Each employee will receive hands-on, in-depth training on the inventory tracking system before beginning their position. Utilizing one on one situational training with the Head Trainer, detailed SOP's with step by step instruction, first hand training on the dispensary floor shadowing with seasoned Patient Consultants & Inventory Staff, as a three-step training process before beginning their position.

Each employee will receive detailed training on how to use and advise patients to use the state board of pharmacy's toll-free telephone line to respond to inquiries from patients, caregivers, and health professionals regarding adverse reactions to medical marijuana and to provide information about available services and assistance.

The Medical Director will conduct an in-person, on-site training with education on signs of addiction or medication abuse. This visual training will also include adverse events and side effects that could take place when using medical marijuana. The Medical Director will be filmed providing this training so future new employees can watch the training video at the inception of being hired. They will receive another one in person, with the yearly training

Employees will receive a security training course where they learn the security SOP's for their facility, as well as policies for adverse events and emergency response SOP's. The in-depth and concise, Inventory, Patient Sales and Security SOP's are given to each new employee in writing as well as covered in an individual initial and continuing education training course.

Employees sign a confidentiality form and are sent home with an Employee Handbook that lays out the expectation of confidentiality. Even though we are not bound by HIPPA we will follow all applicable HIPPA guidelines for patient confidentiality.

Employees receive, as one of the training courses they take, an in-depth training on different form and modes of administration as well as strains of medical marijuana.

Employees will receive foundational and continuing education on the qualifying conditions that medical marijuana can be used to treat. The material used to educate employees on AIDS, amyotrophic lateral

sclerosis, Alzheimer’s disease, cancer, chronic traumatic encephalopathy, Crohn’s disease, epilepsy or another seizure disorder, fibromyalgia, glaucoma, hepatitis C, inflammatory bowel disease, multiple sclerosis, pain that is either chronic and severe or intractable, Parkinson’s disease, positive status for HIV, post-traumatic stress disorder, sickle cell anemia, spinal cord disease or injury, Tourette’s syndrome, traumatic brain injury, and ulcerative colitis, will also include the authorized uses of medical marijuana to treat the listed qualifying conditions. The employee training program will be performed only by a pharmacist, clinical nurse specialist, certified nurse practitioner, physician or physicians assistant.

All Dispensary Support Employees will receive training on how to interact with Law Enforcement effectively as well as the Standard of Excellence expected to always be compliant and prepared for regulatory inspections.

During their On-boarding training, each employee will be given the stipulations and requirement to become and maintain their status as a licensed dispensary employee as well as any requirement set forth by the state board of pharmacy.

Each dispensary employee will have to complete 16 hours of continuing education every 2 years. The continuing education training will include, at a minimum, a background familiarity with patient interaction; appropriate communications skills with seriously or terminally ill patients and their families; a necessary mastery of medical and pharmaceutical complexities that is great enough to at least recognize when a medical professional needs to be involved in the patient's care urgently or emergently.

Considering the above points, the proposed hours of training are below::
• Ohio rules/law: 2 hours
• Qualifying conditions and symptoms: 2 hours
• Short and long-term effects and medicinal benefits of Cannabinoids: 2 hours
• Updated research and/or products that may benefit qualifying patients: 4 hours
o This is the bulk of the training where the employees must have mastery. Discussions on CBD/THC, product form, route of administration, interactions with other medicines, and potential drug interactions with cannabinoids are extremely complicated due to the presence of multiple actives (all cannabinoids and terpenes are actives). These discussions will be a part of their every day patient interaction and guidance.
• Risks and benefits of various forms of administration: 1 hour is sufficient, as there is overlap with other sections
• Safe handling of medical marijuana products: 2 hours
• Customer privacy and rights: 1 hour
• Risks and signs of overuse, abuse, and addiction: 2 hours

Each employee also receives new SOP’s with updates to the current patient symptom tracking system, as that will be revised with software updates, new qualifying conditions, and new research.

Tools for refusing to dispense medical marijuana to a patient or caregiver who appears to be impaired or abusing medical marijuana will be taught in the form of scripting, scenario summaries, medical addiction cues.

An updated guideline for the safe handling of medical marijuana will be thorough and in-depth to give an overview of common industry hazards, current health and safety standards, dispensary best practices and good manufacturing standards.

A training focused on legal issues surrounding the Ohio medical marijuana control program will be a key part of the continuing education for dispensary employees. This legal training will also include any other changes/updates from the State Board of Pharmacy.

The Training manager will schedule and facilitate all trainings. Any patient care, drug interactions, symptom and strain knowledge will be taught by the Medical Director or other medical designee. All legal updates will be taught by the Legal Department. Any dispensary continuing education for day to day operations, customer service and patient experience will be taught by the Director of Onboarding. All the training material will be submitted to the State Board of Pharmacy for review before use.

A training course under each section will be offered every 6 months. At least 3 employees will attend each class, but total number will vary based on where the individual employee falls in their continuing education hours. In the interim new updates to the laws or state system will go out via memo to all employees with a one on one hands-on training so they are adequately prepared and compliant.

A portion of the continuing education will either be in person with the medical director or medical designee, director of on-boarding or legal team. The rest of the information will be via computer. The employees will either read a training document with information or watch a training video. After completing either of those items, they will have to complete a quiz to demonstrate and prove their knowledge.

E-1.1.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in E-1.1. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Worker Training Record.pdf**
NOTE: This applicant uploaded document is the next 11 page(s) of this document.

Worker Training Requirements			
Course Title	**Topics covered**	Worker 1	Worker 2
Business Practices			
	Goal Setting		
	Document Control		
	Advertising Methods		
	Records Management		
Community Relations			
	Community Relations Plan		
Crisis Management			
	Crisis Training and Testing		
General Training			
	Company Policies and Procedures		
	Emergency Procedures		
	Government Laws and Regulations		
	Industry Policies and Standards		
	Labeling and Packaging		
	Product Testing		
	Regulatory Inspections		
	Sanitation and Cleaning Procedures		
	Sexual Harassment		
	Interaction with Law Enforcement		
	Violations and Enforcement		
Health & Safety			
	Health and Safety Risk Assessment		
	Electrical safety, Slip/Trip/Fall Protection, Ergonomics		
	Personal Protective Equipment		
	Accident and Emergency Procedures		
	Hazardous Materials		
Worker Practices			
	Worker Cleanliness		
	Hand Sanitation		
	Wounds and Infections		
	Protective Clothing		
	Prohibited Items		
	Eating and Drinking		
	Smoking and Tobacco Products		
	Control of Drug Use		
	Violence and Weapons		
	Hygiene and Food Handling Safety		

Product Quality			
	Quality Management System		
	Hazard Control Plan		
	Product Classification and Control		
	Product Specifications		
	Control of Contaminants		
	Production Records		
	Rejected and Quarantined Products and Materials		
	Corrective Action Plans		
Sanitation			
	Sanitation Procedures and Training		
	Master Sanitation Schedule		
	Cleaning Equipment and Supplies		
	Cleaning Equipment Identification		
	Sanitation Logs		
	Product Protection During Cleaning		
Waste Management			
	Waste Management Plan		
	Hazardous Materials Disposal		
	Cannabis Waste Disposal		
	Waste Container Control		
Security Training			
	Access Controls – Workers and Visitors		
	Theft/Product Loss		
	Cash Management		
	ID Verification Process		
	Dynamic entry, Robbery		
	Alarms, Panic Buttons		
	Surveillance and video systems		
	Product Transportation		

Worker 3	Worker 4	Worker 5	Worker 6	Worker 7	Worker 8	Worker 9

Date Training Completed						
Worker 10	Worker 11	Worker 12	Worker 13	Worker 14	Worker 15	Worker 16

Worker 17	Worker 18	Worker 19	Worker 20	Worker 21	Worker 22	Worker 23

Worker 24	Worker 25	Worker 26	Worker 27	Worker 28	Worker 29	Worker 30

E-1.2 Summarize how the Applicant's training plan will identify and incorporate advancements in medical marijuana research. Include a description of the frequency with which the training plan will be updated, how new information will be incorporated into the training plan, the method for providing updated training to dispensary employees, and the frequency with which updated training will be provided to dispensary employees. OAC 3796:6-3-19

A designated employee will audit all research outlets deemed informational and trustworthy by the medical director with an emphasis on primary scientific literature accessed through databases such as PubMed. In order to keep pace with rapid advancements in scientific understanding of medical marijuana, cannabinoids, and terpenes as therapeutic agents, literature reviews will be performed monthly at a minimum. Areas of research and information that will be monitored include:

• Effectiveness of strains of medical marijuana for specific conditions based on available scientific literature and anecdotal reports from patients.
• Information on the properties of the cannabinoids and terpenes in selecting products for use
• Basic principles of Absorption, Distribution Metabolism and Excretion (ADME) to help patients better understand the time-effect relationship between consumption and therapeutic effect
• How medical marijuana interacts with the endocannabinoid system
• Methods and forms of consumption or inhalation of medical marijuana
• Signs and symptoms of possible side effects as well as contraindications
• Information regarding signs and symptoms of substance abuse, tolerance, dependency, and withdrawal
• Resources for patients in need of assistance dealing with dependency, abuse, or withdrawal
• Possible impairment with use and operation of a motor vehicle or heavy machinery and tending to children and other individuals
• Risks associated with marijuana use for pregnant and lactating women

In performing literature reviews boolean search terms alone or in combination may include but are not limited to:
• Absorption
• Abuse
• ADME
• Adverse
• Cannibidiol
• Cannabidiolic Acid
• Cannabigerol
• Cannabigerolic Acid
• Cannabis
• Cannabinoids
• CBD
• Tetrahydrocannibinol
• Tetrahydrocannibinolic Acid
• Dependency
• Distribution
• Efficacy
• Endocannabinoid
• Excretion
• Impairment
• Marijuana
• Metabolism
• Terpene

• Therapeutic
• THC
• Withdrawal

All boolean searches will be recorded, correlated with retreived documents of value for reference in performing future searches. The most current research identified will be reviewed, evaluated for study quality, interpreted and summarized. Summaries will be disseminated to all employees via individual memos and added to mandatory continuing education courses held quarterly. During continuing education, key points from the summaries will be explained in greater depth and employees will be encouraged to engage in dialogue on the topic to demonstrate understanding of the concepts and data presented. The facility will also offer quarterly patient education courses that include current research. All information presented during employee training will also be included in updated versions of the patient information booklet and patient education class course material printed quarterly at a minimum.

E-1.2.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in E-1.2. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Training Courses.pdf**
NOTE: This applicant uploaded document is the next 2 page(s) of this document.

Training Courses		
Course Title	**Topics Covered**	**Length (min)**
Business Practices		20
	Goal Setting	
	Document Control	
	Advertising Methods	
	Records Management	
	Workplace Harassment	20
	Community Relations Plan	
Health & Safety		
	Health and Safety Risk Assessment	
	Electrical safety, Slip/Trip/Fall Protection, Ergonomics	
	Personal Protective Equipment	
	Accident and Emergency Procedures	
	Hazardous Materials	
Worker Practices		30 w/out FS
	Worker Cleanliness	
	Hand Sanitation	
	Wounds and Infections	
	Protective Clothing	
	Prohibited Items	
	Eating and Drinking	
	Smoking and Tobacco Products	
	Control of Drug Use	
	Violence and Weapons	
Food Safety	Hygiene and Food Handling Safety	30
Product Quality		
	Quality Management System	
	Hazard Control Plan	
	Product Classification and Control	
	Product Specifications	
	Control of Contaminants	
	Production Records	
	Rejected and Quarantined Products and Materials	
	Corrective Action Plans	
	Product Testing	
	Packaging and Labeling	

Sanitation		
	Sanitation Procedures and Training	30
	Master Sanitation Schedule	
	Cleaning Equipment and Supplies	
	Cleaning Equipment Identification	
	Sanitation Logs	
	Product Protection During Cleaning	
Waste Management		
	Waste Management Plan	20
	Hazardous Materials Disposal	
	Cannabis Waste Disposal	
	Waste Container Control	
Security Program		
	Access Controls Workers and Visitors	
	Theft/Product Loss	
	Cash Management	
	ID Verification Process	15
	Dynamic entry, Robbery	
	Alarms, Panic Buttons	
	Surveillance and video systems	
	Product Transportation	

Patient Care(Patient Care and Education)

E-2.1 Describe how dispensary employees will be trained to provide patient education regarding:

1. Recognizing the signs of abuse or adverse events in the medical use of marijuana
2. Instruction on use of medical marijuana to treat a qualifying condition
3. Risks associated with medical marijuana, including possible drug interactions
4. Guidelines for support to patients related to the patient's symptoms
5. Guidelines for refusing to provide medical marijuana to an individual who appears to be impaired or abusing medical marijuana. Include the sources of the training and the sources' qualifications to provide such training.

Please reference OAC 3796:6-3-19 for more information.

Employees will receive training at the time of hire as well as continuing education on providing patient education. This training will include teaching them how to recognize the signs of medical marijuana abuse or adverse events in the medical use of marijuana. These signs can be recognized by the employee via patient interaction and patient feedback (verbally or on a symptom tracking form). The following are 10 points the employees will be educated on to both recognize and be able to further educate the patients on their usage and awareness:

* Medical marijuana tolerance and withdrawal
* Unable to cut down or stop medical marijuana use
* Lots of time spent abusing medical marijuana for inappropriate uses
* Using medical marijuana to escape from problems
* Choosing relationships and activities based on whether or not you will be able to use medical marijuana

Employees will also be educated on adverse events in the medical use of marijuana. This education will happen at their initial training, at time of hire, as well as during their continuing education classes. Employees will then educate patients during their visits on side effects, drug interactions and adverse events. In addition, side effects and drug interactions will be listed out as part of the patient education booklet every patient receives during their initial visit.

Special Precautions & Warnings:

Medical marijuana may drop blood pressure by as much as 40 points. Therefore, check your blood pressure and pulse before and after use and when you feel the medication has reached peak effect. Rapid heart rate may be worsened when combined with other drugs that have anticholinergic effects such as the tricyclic antidepressants: desipramine, amitriptyline, nortriptyline.

Pregnancy and breastfeeding: Medical Marijuana is unsafe when taken by mouth or smoked during pregnancy (Ohio law prohibits use of medical marijuana by smoking or combustion). Medical marijuana passes through the placenta and can slow the growth of the fetus. Using medical marijuana, either by mouth or by inhalation is likely unsafe during breastfeeding. THC in medical marijuana passes into breast milk.

Surgery:

Medical marijuana affects the central nervous system. It may slow the central nervous system too much when combined with anesthesia and other medications during and after surgery. Stop using medical marijuana at least 2 weeks before a scheduled surgery.

Short Term Side Effects:

* Memory Loss/Cognitive Agility Decreased
* Loss of Coordination
* Impaired Driving Ability
* Mental Confusion and Hallucinations (In High Doses)
* Sedation
* Blood-Shot Eyes

* Increased Heart Rate
* Decreased Blood Pressure

Employees will be trained on how to interact with patients and situational awareness to be able to both recognize and educate the patient on signs of abuse or adverse events.

Employees will receive training on each of the qualifying conditions from the medical director or medical director designee when they are hired. The medical director or medical director designee will always be available to patients and employees during business hours to give any further and/or specific guidance to a patient.

Examples of the training material is quoted below for some of the qualifying conditions.

ALZHEIMER'S DISEASE – Medical marijuana has been demonstrated to prevent cell death. The THC found in medical marijuana inhibits the primary marker of this terrible disease. When patients refuse food, medical marijuana can stimulate appetite, a positive result that carries over to many other conditions where a patient may experience a loss of appetite either from an ailment, or treatment.

CANCER – "Possibly the greatest harm-reducing potential afforded by cannabinoids comes from their use by cancer patients," according to Harm Reduction Journal, an online peer-reviewed medical journal. They go on to state "numerous cancer types are killed in cell cultures in animals by cannabinoids. For example, cannabinoids kill the cancer cells of various lymphoblastic malignancies such as leukemia, skin cancer, glioma, breast and prostate cancer… thyroid cancer, and colorectal cancer." More research is needed however, as cannabinoids can promote cancer in other cells, particularly in the lungs.

GLAUCOMA – There have been short-term studies that indicate medical marijuana lowers intraocular pressure, sometimes as much as 25%. According to the National Institute of Health, "some derivatives of marijuana lowered intraocular pressure when administered orally, intravenously, or by smoking, but not when topically applied to the eye."

MULTIPLE SCLEROSIS (MS) – Cannabinoids have been proven to function as 'homeostatic modulators of the immune system' which suggests therapeutic potential of medical marijuana to provide relief to people suffering from neurological diseases like MS (Harm Reduction Journal).

TOURETTE'S SYNDROME – In one study, a subject's total tic severity score fell from 41 to 7. This finding led to further studies all solidifying the medicinal benefits of medical marijuana. One such study also made note that after long-term cannabinoid treatment, not a single subject had any adverse effects on their 'learning, recall or verbal memory' and goes on to recommend medical marijuana when other drugs fail to show similar results. (Muller-Vahl et al. 1999. Treatment of Tourette's syndrome with delta-9-tetrahydrocannabinol. American Journal of Psychiatry)

Employees will receive initial and ongoing training on the risks associated with medical marijuana, including possible drug interactions. This training will include some of the following:

Polydrug use is using more than one drug at the same time. People use drugs in combination to either increase their intoxication, or to increase the effect of the first drug taken.

Sedative medications (CNS depressants)

Interaction Rating: Major – Do not take this combination.

Medical marijuana might cause sleepiness and drowsiness. Medications that cause sleepiness are called sedatives. Taking medical marijuana along with sedative medications might cause too much sleepiness.

Some sedative medications include clonazepam (Klonopin), lorazepam (Ativan), phenobarbital (Donnatal), zolpidem (Ambien), and others.

Theophylline

Interaction Rating: Major – Do not take this combination.

Taking medical marijuana might decrease the effects of theophylline. But there isn't enough information to know if this is a big concern.

Employees will be educated on ways to alleviate patient's symptoms and the multiple ways products can be used to achieve relief.
The following are a few examples:
* Tinctures can also be applied topically on areas dealing with symptoms of pain, stiff joints, tight muscles, or over the temples during headaches.
* Indica strains relieve symptoms but will also make you sleepy, some may cause severe sedation.
* Sativa strains are said to be energizing, focusing and inspirational, but can occasionally cause anxiety.

Further Education Items:
* Patients who experience respiratory disorders that could be affected by vape inhalation should first try alternatives (Example: edibles, topicals, and patches).
* Ohio Law PROHIBITS use of Medical Marijuana by smoking or combustion.
* No Medical Marijuana may be consumed on dispensary site.
* If you have a history of adverse side effects in using medical marijuana, please consult a physician before use.
* If you are pregnant or may become pregnant, please do not use medical marijuana. The cannabinoids may actually transfer to the child or fetus via your ingestion. Adequate studies have not been made to prove that medical marijuana has no effect on the fetus or child.
* DO NOT drive or operate heavy machinery under the influence of marijuana.
* The telephone contact for poison control, the local hospitals address, and an addiction hotline.
* Patients who have reached their 90 day allotment of medical marijuana will be denied any further sales until a new recommendation to treat has been given

Patients who have reached their 90 day allotment and will not receive further medical marijuana and will be denied a sale that day. These "checked-in" patients are to be notified their allotment amount has been reached. Once the establishment of ineligibility has been conferred to the patient, a "Denial of Service - REASON" notation must be made against the transaction receipt on the point of sale software. Other denial reasons besides reaching the 90 day allotment maximum include erratic behavior, intoxicated or invalid card.

In the patient education booklet given to each patient on the first visit, there will be a symptom tracking form. Patients will be offered this form at every visit, which will document strain/product, date, time of medicating, onset time, effectiveness scale, duration the medication is effective, any negative effects and any notes. This information can show many trends and pertinent data which can be reviewed during the patient education at the next visit. It can then help to choose the proper fitting medication as well as have the data transposed into the POS system to stay electronically with the patient file.

A website may be developed to include patient education material as described above. The website will also include:
* Business name
* Business address
* Contact information
* Services provided
* Price of all medical marijuana products offered

E-2.1.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in E-2.1. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

No response provided by applicant

E-2.2 Describe the Applicant's processes, procedures and controls addressing reports of adverse events. Include, at a minimum, a description of:

1. How reports will be documented
2. The circumstances that will require reports of adverse events will be reported to a cultivator, processor, and / or the State Board of Pharmacy
3. The time frame for which to provide such reports

All consumer complaints will be documented and the Product Recall Coordinator notified immediately upon receipt of the complaint. Written records will include, but are not limited to, the following:
1. Complaint number (for tracking purposes)
2. Name and description of product
3. Batch, lot, or control number
4. Complaint date
5. Manner in which the complaint was received
6. Complainant's name, address, telephone No.
7. Nature of complaint and how product was used (if applicable)
8. Findings of investigation and follow-up action
9. All correspondence associated with complaint
10. Records of reports made to the state board of pharmacy and any information provided regarding adverse events and available services.
11. Dated reviewer's initials

Records of investigations involving complaints of possible hazards to health must be complete showing that all requirements for the investigation were met. These records must also show dates, times and the names of all individuals involved with the investigation. Complaints may be categorized by the Product Recall Coordinator as one of the following:

Class I – This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
Class II – This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.
Class III – This is a situation where the use of the product will not cause adverse health consequences.
Product complaints falling into Class I and Class II will initiate notification of the State Board of Pharmacy within 24 hours of (3796:6-3-11) discovery and classification. Class III recalls require that customers be notified. Additionally, The state board of pharmacy shall establish a toll-free telephone line to respond to inquiries from patients, caregivers, and health professionals regarding adverse reactions to medical marijuana and to provide information about available services and assistance. The board may contract with a separate entity to establish and maintain the telephone line on behalf of the board.

Patient Care(Patient Care Facilities)

E-3.1 Describe the adequacy of the size of the proposed dispensary to serve the needs of patients and caregivers, including building and construction plans with supporting details. Such plans shall illustrate, at a minimum, the size and location of the following within the prospective dispensary location:

1. The dispensary department
2. Restricted access areas
3. Waiting room
4. Patient care areas or other areas designated for patient and caregiver consultation and instruction. Include a summary of the patient flow through each area, the maximum patient and caregiver occupancy in each area at any given time, the amount of time the Applicant expects to interact with both new and returning patients, and the number of dispensary employees who will staff each area

Please reference OAC 3796:6-2-02 for more information.

[redacted]

[redacted]

E-3.1.1 Applicants may include images or diagrams, in PDF format, demonstrating the measures described in E-3.1. The images or diagrams may contain a brief descriptive caption. Additional language responding to the question will not be considered.

Uploaded Document Name: **Final Ohio Valley Wellness Dispensary Floorplan color coded(3).pdf**
NOTE: This applicant uploaded document is the next 1 page(s) of this document.

Patient Care(Dispensary Operating Hours)

E-4.1 By selecting "Yes", the Applicant attests that it will make the dispensary available to patients and caregivers to purchase medical marijuana for a minimum of 35 hours per week, between the hours of 7 am and 9 pm, except as authorized by State Board of Pharmacy. OAC 3796:6-3-03

YES

E-4.2 Provide the proposed hours of operation during which the prospective dispensary will available to dispense medical marijuana to patients and caregivers. (Information only) OAC 3796:6-3-03

Tuesday - Saturday 11am - 7pm (Proposed hours may be extended at a later date to accommodate patient need, pending State approval)

Patient Care(Patient Information)

E-5.1 By selecting "Yes", the Applicant attests that it will post a sign directing patients and caregivers with medical marijuana inquiries or adverse reactions to the toll-free hotline established by the State Board of Pharmacy. OAC 3796:6-3-15

YES

E-5.2 By selecting "Yes", the Applicant attests that it will make information regarding the use and possession of medical marijuana available to patients and caregivers. The Applicant agrees to submit all such information to the State Board of Pharmacy prior to being provided to patients and caregivers. OAC 3796:6-3-15

YES

Attestations and Acknowledgements(Attestations and Acknowledgements)

F-1.1 Fill out and attach the "Trade Secret Form" to Question F-1.1, specifying the question and / or attachment references of the application submission that are exempt from disclosure under Ohio public records law and articulate how the information meets the definition of "trade secret" under Ohio Revised Code section 1333.61(D). If no material is designated as trade secret information, a statement of "None" should be listed on the form.

Uploaded Document Name: **Trade Secret.pdf**
NOTE: This applicant uploaded document is the next 2 page(s) of this document.

STATE OF OHIO BOARD OF PHARMACY

Ohio Medical Marijuana Control Program
Dispensary Application

Trade Secret Form

(Attachment to Application Section F-1.1)

This form must be signed by an individual who may legally sign for the Applicant. The form must be printed and signed with an original, wet-ink signature. Electronic or digital signatures are not acceptable. Scan and attach a copy of the signed form, in PDF format, in response to Question F-1.1 of the online Application.

Business Name of Applicant: Ohio Valley Wellness LLC

The undersigned is an Applicant for a medical marijuana Dispensary license. The Applicant understands that the State of Ohio Board of Pharmacy is an entity of the State of Ohio and any documents or data submitted to the State of Ohio may be disclosed by the State pursuant to an Ohio Public Records Act request.

While the Ohio Public Records Act permits certain exclusions from disclosure, Applicant understands the State makes no guarantee or promises that such data will not be disclosed. Applicant has reviewed the Ohio Public Records Act, as well as relevant case law.

Applicant understands that the documents or data it provides to the State of Ohio may not be confidential, or if confidential, may or may not be disclosed pursuant to an Ohio Public Records Act request.

Applicant understands that there are additional requirements in order to claim a trade secret record exception. Applicant understands that materials consisting of trade secrets must be clearly marked, specifying the pages of the application question, attachment name related to the material that is to be restricted and justifying the trade secret designation for each item.

Printed Name of Authorized Representative

Jennifer Picha

Signature	Date
Jennifer J Pal	11/15/17

Question Number	Attachment Reference	Justification for Excluding as Trade Secret

F-1.2 To be considered complete, each application must be submitted with an Attestation and Release Authorization. The form must be completed by a Prospective Associated Key Employee who may legally sign for the Applicant and who can verify the information provided in the application is true, correct, and complete.

This response has been entirely redacted