Architectural Resources
505 Franklin Street
Buffalo, NY 14202

303 West 13th Street
New York, NY 10014
716 883-5566
716 883-5569 fax
mail@archres.com

Consultants

M/E Engineering
60 Lakefront Blvd, Suite 320
Buffalo, NY 14202

716-845-5092
716-845-6187 fax

C&S Companies
141 Elm Street, Suite 100
Buffalo, NY 14203

716-847-1630
716- 847-1454 fax

Drawing List

Architectural

Kinex Supportive Pharmaceuticals Buffalo Manufacturing Facility

Lackawanna, NY 14218

Schematic Design
06.02.2015
A | r 561.01

Project Location

Kinex Supportive Pharmaceuticals Buffalo
Manufacturing Facility
561.01
06.02.2015
Schematic Design

Redacted pursuant to N.Y. Public Officers Law, Art.6

Redacted pursuant to N.Y. Public Officers Law, Art.6

Redacted pursuant to N.Y. Public Officers Law, Art.6

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Redacted pursuant to N.Y. Public Officers Law, Art.6

Redacted pursuant to N.Y. Public Officers Law, Art.6

Redacted pursuant to N.Y. Public Officers Law, Art.6

Kinex
Pharmaceuticals

June 1, 2015

New York State Department of Health
Bureau of Narcotic Enforcement
Medical Marijuana Program
150 Broadway
Albany, New York 12204

Re: Michael Murphy – Board Member of Kinex Pharmaceuticals, Inc. ("Kinex")

Dear Sirs:

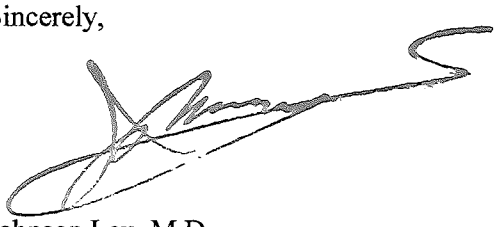
This letter is being provided in connection with the submission of an application (the "Application") by Kinex Supportive Pharmaceuticals, LLC ("Applicant") to the New York State Department of Health for a franchise to manufacture and dispense approved medical marijuana products in New York State. The Applicant is a wholly-owned subsidiary of Kinex. As you know, the Application requires all Board Members of Kinex to submit an affidavit with the Application.

All of Kinex's Board Members except Michael Murphy (http://www.kinexpharma.com/our-company/board-of-directors/) have submitted the required affidavit. Unfortunately for Kinex, Mr. Murphy's law firm, DLA Piper, will not permit him to continue to serve as Board Member of Kinex in the event that Applicant is awarded a franchise to manufacture and dispense medicinal marijuana (the "Franchise Award").

Therefore, in the event that Applicant receives the Franchise Award, Mr. Murphy will immediately resign from the Board of Kinex. Mr. Murphy has not resigned as of the date of this letter because he is a valuable Board Member of Kinex, and Kinex does not wish to lose his counsel and skills in the event that the Applicant does not receive the Franchise Award.

If you have any questions about the foregoing or require additional comfort that Mr. Murphy will resign in the event Applicant receives the Franchise Award, do not hesitate to call Kinex's corporate counsel Christian J. Henrich, Esq. of Woods Oviatt Gilman, LLP at (716) 249 – 3211.

Sincerely,



Johnson Lau, M.D.
Chairman of the Board
Kinex Pharmaceuticals, Inc.

OFFICE OF THE MAYOR
CITY OF LACKAWANNA

Hon. Geoffrey M. Szymanski ~ Mayor

June 1, 2015

Mr. Jody Miller, Director of Trade and Distribution
Kinex Supportive Pharmaceuticals LLC
c/o 4 Front Consulting Group Inc.
2820A One Seneca Tower
Buffalo, New York 14203-2897

RE: Kinex Supportive Pharmaceuticals LLC

Dear Mr. Miller,

On behalf of the City of Lackawanna kindly, accept this correspondence as evidence of our complete support for the Kinex Supportive Pharmaceuticals LLC proposed project to develop and manage a medical marijuana cultivation-manufacturing facility in the City of Lackawanna (the "Project").

The Project is proposed for an improved site that is located on a portion of the former Bethlehem Steel property known as 2303 Hamburg Turnpike, Lackawanna, NY (the "Property"). The redevelopment of this abandoned manufacturing building, along with the proposed employment opportunity, will add a significant and valuable piece to the revitalization of the City of Lackawanna.

The City of Lackawanna welcomes this opportunity to be in the forefront of this important growing medical program that is intended to bring positive impacts on the lives of those who unfortunately are faced with major illnesses.

The Property is properly zoned for the activities associated with the operation of cultivation-manufacturing facility. Additionally, the property is currently serviced with all appropriate utilities such as electrical, water, and sewer.

Please be advised that the Project will receive the fullest cooperation from the City in addressing the permitting process and all related issues with the building permit approvals and related issues. In the event there are any questions or if I can be of further service I encourage you to contact me.

Respectfully submitted,

Geoffrey M. Szymanski, Mayor

Hon. Geoffrey M. Szymanski ~ Mayor
City of Lackawanna, New York
714 Ridge Road ~ Room 301 ~ Lackawanna, New York 14218 ~ (716) 827-6464 ~ FAX (716) 827-6678
http://www.lackawannany.gov
mayor@lackny.com

BRIAN HIGGINS
26TH DISTRICT, NEW YORK

COMMITTEE ON HOMELAND SECURITY
RANKING MEMBER
SUBCOMMITTEE ON
COUNTERTERRORISM AND INTELLIGENCE
SUBCOMMITTEE ON
EMERGENCY PREPAREDNESS,
RESPONSE, AND COMMUNICATIONS

COMMITTEE ON FOREIGN AFFAIRS
SUBCOMMITTEE ON THE
MIDDLE EAST AND NORTH AFRICA
SUBCOMMITTEE ON EUROPE,
EURASIA, AND EMERGING THREATS

Congress of the United States
House of Representatives
Washington, DC 20515–3226

2459 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3306
(202) 226-0347 (FAX)

726 EXCHANGE STREET
SUITE 601
BUFFALO, NY 14210
(716) 852-3501
(716) 852-3929 (FAX)

640 PARK PLACE
NIAGARA FALLS, NY 14301
(716) 282-1274
(716) 282-2479 (FAX)

higgins.house.gov

May 28, 2015

Mr. Jody Miller
Chief Operating Officer
Kinex Supportive Pharmaceuticals LLC
c/o 4Front Consulting Group
2820A One Seneca Tower
Buffalo, New York 14203-2897

Dear Mr. Miller,

I am pleased to write in support of Kinex Supportive Pharmaceuticals application for a license from the New York State Department of Health to develop a medical marijuana cultivation-manufacturing facility in Lackawanna, New York. This proposal encompasses your commitment to producing high quality medicine as well as ensuring patient and public safety.

The strength of your submission rests on your extensive knowledge of specialty pharmacy which is critical to the success of this effort to produce this new medicine that will prove instrumental in treating a number of major illnesses. You are to be credited for your outreach to the local leadership of Lackawanna and organized labor as the successful conversion of a former steel making site to the exciting industry of botanical medicines helps to re-brand and re-energize the entire region of Western New York as home to increasing and diverse employment and educational opportunities.

And most importantly, with a successful application and implementation, people in need can have every confidence that the Kinex facility will provide a safe, secure and state sanctioned product that will bring relief from pain and hope for the future. I wish you every success with this very worthy application.

Sincerely,

BRIAN HIGGINS
Member of Congress

THE SENATE
STATE OF NEW YORK
ALBANY 12247

SENATOR PATRICK M. GALLIVAN
59TH DISTRICT

May 29, 2015

Howard A. Zucker, Commissioner
New York State Department of Health
Corning Tower
Empire Plaza
Albany, New York 12237

Dear Commissioner Zucker,

The purpose of this letter is to support the awarding of one of the licenses for the production and dispensing of medical marijuana in New York State to an organization that plans to locate their cultivation/manufacturing center in Erie County. Erie County, which is the home of the state's second most populated city and the center of the second largest metropolitan region in the state, is ideally situated in western New York for this purpose as it would provide direct and tangible benefits to the constituents we serve.

Western New York residents would benefit by having greater access to the essential medication that they need. Due to the requirement that a dispensary cannot be located in a county that neighbors a county where a growing/dispensary is located, a large population would have to travel long distances to receive the medication they need if a license is not awarded to Erie County. Distant dispensaries would make it exceedingly burdensome to obtain medication.

Additionally, a dispensary location and growing facility would have a significant and positive economic impact in Erie County, where the economic recovery has lagged behind most other areas of the state. New York State has mandated that a 7% excise tax be paid on gross receipts by the grower. From this tax revenue, 22.5% of it will go to the county where the marijuana is grown, and another 22.5% of it will go to the county where it is sold or dispensed. This additional revenue would help to relieve the excessive tax burden already suffered by our residents. In addition, the creation of badly needed jobs would also help to speed the economic recovery.

Kinex Supportive Pharmaceuticals LLC has indicated its desire to locate a medical marijuana cultivation/manufacturing center at the former Bethlehem Steel site in Lackawanna, along with a dispensary in Cheektowaga. The company, which has a strong background in the production of pharmaceuticals, has also expressed a commitment to safety and security and to comply with all local laws and ordinances. I respectfully request that you consider these factors as you contemplate the awarding of medical grade cannabis licenses in New York State. Please do not hesitate to contact my office should you have any questions.

Sincerely,

Patrick M. Gallivan
Senator – 59th District

THE ASSEMBLY
STATE OF NEW YORK
ALBANY

SEAN M. RYAN
Assemblyman 149th District

936 Delaware Avenue, Suite 005
Buffalo, New York 14209
716-885-9630
FAX: 716-885-9636

Room 540
Legislative Office Building
Albany, New York 12248
518-455-4886
FAX: 518-455-4890

ryans@assembly.state.ny.us

June 1, 2015

Mr. Jody Miller
Director of Trade and Distribution
Kinex Supportive Pharmaceuticals LLC
c/o 4Front Consulting Group Inc.
2820 A One Seneca Tower
Buffalo, New York 14203-2897

Dear Mr. Miller:

You recently presented your company's plan to develop a cultivation-manufacturing center at the former Bethlehem Steel site in Lackawanna, NY. As you are aware, this site is in my district. You have made a commitment to a brownfield site in an abandoned building, which you will renovate for the production of medical marijuana. Your efforts will bring new jobs and new skills to Lackawanna, supporting the economic recovery of the city. Further, if awarded a license, you will be a major participant in the medical treatment of many severe illnesses in our state. You and your WNY partners have a thoughtful and well-designed plan to provide high quality medicine with recognition of patient and public safety.

Please let this letter serve as my support for your efforts. I look forward to working with you in the future.

Sincerely,

Sean M Ryan

SEAN M. RYAN
MEMBER OF ASSEMBLY

ROBIN SCHIMMINGER
140th District

THE ASSEMBLY
STATE OF NEW YORK
ALBANY

CHAIRMAN
Committee on Economic Development,
Job Creation, Commerce and Industry

COMMITTEES
Codes
Health
Ways & Means

May 29, 2015

Mr. Jody Miller
Director of Trade and Distribution
Kinex Supportive Pharmaceuticals LLC
c/o 4Front Consulting Group Inc.
2820A One Seneca Tower
Buffalo, New York 14203

Dear Mr. Miller:

Please let this letter serve as confirmation of my support for your proposal to develop a cultivation-manufacturing center for medical marijuana in Erie County.

I understand that you have chosen the former Bethlehem Steel site to create a state-of-the-art growing facility. Your efforts will be bring needed jobs to Lackawanna and the Buffalo Niagara region, and you will be making a contribution to those patients in need of relief from major illnesses. Your well-designed plan to cultivate, process, and dispense this new medicine is based on your long history in the pharmaceutical industry. You have shown that you are committed to developing a high quality, safe medicine, while recognizing the importance of public safety.

I look forward to working with you in the future.

Sincerely,

Robin Schimminger

RS/vkk

3514 Delaware Avenue, Kenmore, New York 14217-1298, (716) 873-2540

Room 847, Legislative Office Building, Albany, New York 12248-0001, (518) 455-4767

BRIAN HIGGINS
26TH DISTRICT, NEW YORK

COMMITTEE ON HOMELAND SECURITY
RANKING MEMBER
SUBCOMMITTEE ON
COUNTERTERRORISM AND INTELLIGENCE
SUBCOMMITTEE ON
EMERGENCY PREPAREDNESS,
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NIAGARA FALLS, NY 14301
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(716) 282–2479 (FAX)

higgins.house.gov

May 28, 2015

Mr. Jody Miller
Chief Operating Officer
Kinex Supportive Pharmaceuticals LLC
c/o 4Front Consulting Group
2820A One Seneca Tower
Buffalo, New York 14203-2897

Dear Mr. Miller,

I am pleased to write in support of Kinex Supportive Pharmaceuticals application for a license from the New York State Department of Health to develop a medical marijuana cultivation-manufacturing facility in Lackawanna, New York. This proposal encompasses your commitment to producing high quality medicine as well as ensuring patient and public safety.

The strength of your submission rests on your extensive knowledge of specialty pharmacy which is critical to the success of this effort to produce this new medicine that will prove instrumental in treating a number of major illnesses. You are to be credited for your outreach to the local leadership of Lackawanna and organized labor as the successful conversion of a former steel making site to the exciting industry of botanical medicines helps to re-brand and re-energize the entire region of Western New York as home to increasing and diverse employment and educational opportunities.

And most importantly, with a successful application and implementation, people in need can have every confidence that the Kinex facility will provide a safe, secure and state sanctioned product that will bring relief from pain and hope for the future. I wish you every success with this very worthy application.

Sincerely,

BRIAN HIGGINS
Member of Congress

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Kinex Pharmaceuticalas, Inc. | 3. Title: N/A

4. Briefly describe the role of this person or entity in the proposed registered organization:

Kinex Pharmaceuticals, Inc., a Delaware corporation, is the parent company and 100% owner of Kinex Supportive Pharmaceuticals, LLC.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☐ Yes ☑ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc. is the parent company and 100% owner of QuaDPharma, LLC, which offers services for manufacturing, testing and stability of drugs. Neither Kinex Pharmaceuticals, Inc. nor QuaDPharma, LLC have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: 716-898-8626	9. Fax: 866-687-8514
10. Email: info@kinexpharma.com	
11. Residence Address: 701 Ellicott Street	
12. City: Buffalo	13. State: NY / 14. ZIP Code: 14203

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: August 2013 To: Present	Name and Address of Business: Kinex Pharmaceuticals (HK) Ltd. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott St., Buffalo, NY 14203	
Business Type: Hong Kong corporation	Office Held/Nature of Interest: 100% owner	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: August 2013 To: Present	Name and Address of Business: Kinex Therapeutics (HK) Ltd. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott St., Buffalo, NY 14203	
Business Type: Hong Kong corporation	Office Held/Nature of Interest: 100% owner	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: September 2014 To: Present	Name and Address of Business: QuaDPharma LLC 11342 Main Street, Clarence, New York 14031	
Business Type: Delaware Limited Liability Co.	Office Held/Nature of Interest: 100% owner	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: January 2015 To: Present	Name and Address of Business: Trans PKPD, LLC. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott St., Buffalo, NY 14203	
Business Type: Delaware Limited Liability Co.	Office Held/Nature of Interest: 100% owner	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: March 2015 To: Present	Name and Address of Business: Meridian East, Ltd. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York 14202	
Business Type: British Virgin Islands Corp	Office Held/Nature of Interest: 100% owner	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: May 2015 To: Present	Name and Address of Business: Kinex Supportive Pharmaceuticals, LLC c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York14202	
Business Type: NY Limited Liability Company	Office Held/Nature of Interest: 100% owner	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: March 2015 To: Present	Name and Address of Business: Excel Bloom Ltd. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York14202	
Business Type: British Virgin Islands Corp	Office Held/Nature of Interest: wholly owned	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: March 2015 To: Present	Name and Address of Business: Kinex Polymed (HK) c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York 14202	
Business Type: Hong Kong Corporation	Office Held/Nature of Interest: wholly owned	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: April 2015 To: Present	Name and Address of Business: Bioski Ltd. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York14202	
Business Type: British Virgin Islands Corp	Office Held/Nature of Interest: wholly owned	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: April 2015 To: Present	Name and Address of Business: Goldenwood Ltd. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York14202	
Business Type: British Virgin Islands Corp	Office Held/Nature of Interest: wholly owned	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: May 2015 To: Present	Name and Address of Business: Polymed Therapeutics, Inc. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York14202	
Business Type: Corporation	Office Held/Nature of Interest: wholly owned	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: May 2015 To: Present	Name and Address of Business: Taihao Ltd. c/o Kinex Pharmaceuticals, Inc., 701 Ellicott Street, Buffalo, New York14202	
Business Type: Hong Kong Corporation	Office Held/Nature of Interest: wholly owned	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: 6/1/2015
Notary Name: Flint D. Besecker Chief Operating Officer	Notary Registration Number: 02BA6290225
Notary (Notary Must Affix Stamp or Seal)	Date: 6-1-15

TERESA BROPHY BAIR
Notary Public, State of New York
Qualified in Erie County
My Commission Expires October 7, 2017

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Mandra Health, LTD. ("Mandra")

3. Title: N/A

4. Briefly describe the role of this person or entity in the proposed registered organization:

Mandra is a 17.35% (on a fully diluted basis) owner of Kinex Pharmaceuticals, Inc., the parent company of Kinex Supportive Pharmaceuticals, LLC. Mandra will have no role with Kinex Supportive Pharmaceuticals, LLC other than having a 17.35% ownership interest in Kinex Pharmaceuticals, Inc. No employee or board member of Mandra serves as an officer or director of Kinex Pharmaceuticals, Inc.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☐ Yes ☑ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☐ Yes ☑ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc. is the sole business which manufactured or distributed drugs in the preceding 10 years in which Mandra has had ownership or management.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: 852-2556-0668	9. Fax: 852-3113-8252
10. Email: tangbkh@mandra.hk	
11. Residence Address: 10th Floor, Fung House, 19-22 Connaught Road Central	
12. City: Hong Kong	13. State: / 14. ZIP Code: N/A

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: March 2014	Name and Address of Business: Kinex Pharmaceuticals, Inc. 701 Ellicott Street, Buffalo, New York 14202	
To: Present		
Business Type: Delaware Corporation	Office Held/Nature of Interest: 17.35% owner	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date:
Notary Name:	Notary Registration Number:
Notary (Notary Must Affix Stamp or Seal)	Date:

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

I, Lap-yi Hung, solemnly, sincerely and truly declare and affirm that the contents of my affidavit are true.
Affirmed in Hong Kong on 1 June, 2015
Before me

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

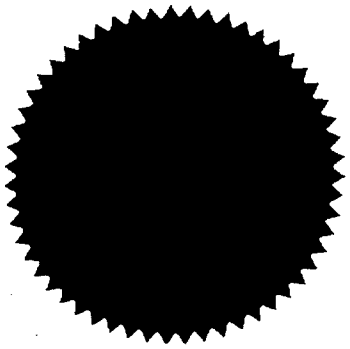
Signature:	Date:
Notary Name:	Notary Registration Number:
Notary (Notary Must Affix Stamp or Seal) CHEUNG WAI LEUNG EDWARD Notary Public, Hong Kong	Date: - 1 JUN 2015

NOTARIAL CERTIFICATE

Country : The People's Republic of China)
City : The Hong Kong Special)
Administrative Region) s.s.

On this 1st day of June in the year Two Thousand and Fifteen before me **CHEUNG WAI LEUNG EDWARD, NOTARY PUBLIC** duly admitted and sworn, practising at 22nd Floor, World Wide House, 19 Des Voeux Road Central, the Hong Kong Special Administrative Region of the People's Republic of China, personally came and appeared **ZHANG SONGYI** (surname first) proved to me on the basis of satisfactory evidence to be the affirmant named in the **AFFIDAVIT** hereunto annexed **WHO** in my presence by solemn affirmation by him taken in due form of law affirmed to the truth of the several statements matters and things mentioned and contained in the said affidavit.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office in Hong Kong Special Administrative Region of the People's Republic of China aforesaid the day and year first written.



CHEUNG WAI LEUNG EDWARD
Notary Public, Hong Kong Special Administrative Region
My commission expires at death

CWL/CWL/CWL/9711/18/15(75)

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Flint D. Besecker

3. Title: N/A

4. Briefly describe the role of this person or entity in the proposed registered organization:

Mr. Besecker is currently the Chief Operating Officer and Board Director of Kinex Pharmaceuticals,Inc., the sole owner of Kinex Supportive Pharmaceuticals, LLC. As such, Mr. Besecker has oversight of all pharmaceutical operating platforms globally. Mr. Besecker also leads the functional areas such as Accounting, Legal, Human Resources and IT. Mr. Besecker will have no direct role in Kinex Supportive Pharmaceuticals, LLC other than serving as member of the Board Directors and COO of Kinex Pharmaceuticals, Inc.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☐ Yes ☑ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc.

I am the COO and a member of the Board Directors of Kinex Pharmaceuticals, Inc..

Neither Kinex Pharmaceuticals, Inc. nor I have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
Canisius College	2001 Main Street Buffalo, New York 14208	1985	1988	B.S. Accounting	May 1988
University of San Diego	5998 Alcala Park San Diego, CA 92110	1984	1985	N/A	

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date
Certified Public Accountant	068579	NYS Education Department	October 1992	Inactive

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Appendix A:

Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Redacted pursuant to N.Y. Public Officers Law, Art.6

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ **Yes** ☐ **No**

From: July 2013	Name and Address of Business: Kinex Pharmaceuticals, Inc. 701 Ellicott Street, Buffalo, New York 14203	
To: Current		
Business Type: pharmaceutical development	Office Held/Nature of Interest: Board Director	☑ **open** ☐ **closed** ☐ **proposed**
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: July 2012 To: Current	Name and Address of Business: Ameris Acquisitions 1114 17th Avenue, Suite 205, Nashville, TN 37212	
Business Type: Hospital services	Office Held/Nature of Interest: Board Director	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: June 2010 To: Current	Name and Address of Business: Smith Hospital of Georgia 4280 North Valdasta Road, Valdasta, Georgia 31602	
Business Type: Hospital	Office Held/Nature of Interest: Board Director	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: May 2008 To: January 2011	Name and Address of Business: Allion Healthcare 1660 Walt Whitman Road, Suite 105, Melville, NY 11747	
Business Type: Pharmacy	Office Held/Nature of Interest: Board Director	☐ open ☑ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: 6/1/2015
Notary Name:	Notary Registration Number: 02BA6290225
Notary (Notary Must Affix Stamp or Seal) TERESA BROPHY BAIR **Notary Public, State of New York** **Qualified in Erie County** **My Commission Expires October 7, 2017**	Date: 6-1-2015

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Johnson Yiu-Nam Lau

3. Title: N/A

4. Briefly describe the role of this person or entity in the proposed registered organization:

Mr. Lau is a director of Kinex Pharmaceuticals, Inc., which is the sole owner of Kinex Supportive Pharmaceuticals, LLC. Mr. Lau will have no direct role in Kinex Supportive Pharmaceuticals, LLC other than serving on Kinex Pharmaceuticals, Inc.'s Board.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☐ Yes ☑ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc.

Currently Chief Executive Officer and Chairman of the Board.

Neither Kinex Pharmaceuticals, Inc. nor I have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax: [redacted]
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
University of Hong Kong	Pokfylam Hong Kong	1979	1984	MB, BS	1984
University of Hong Kong	Pokfylam Hong Kong	1989	1992	M.D.	1992
Royal College of Physicians	11 St. Andrews Place Regent's Park London NW1 4LE		1987	MRCP	1987
Royal College of Physicians	11 St. Andrews Place Regent's Park London NW1 4LE		2004	FRCP	2004

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Name of Employer:
Type of Business:

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: 2004	Name and Address of Business: Kinex Pharmaceuticals, Inc. 701 Ellicott Street, Buffalo, New York 14203	
To: Current		
Business Type: Delaware Corporation	Office Held/Nature of Interest: Chairman/CEO	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: 2007 To: 2014	Name and Address of Business: Xenobiotic Laboratories 107 Morgan Avenue, Plainsboro, New Jersey 08536	
Business Type: Corporation	Office Held/Nature of Interest: Chairman	☐ open ☑ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: 2004 To: 2013	Name and Address of Business: Chelsea Therapeutics International 3650 Toringdon Way, Suite 200, Charlotte, NC 28277	
Business Type:	Office Held/Nature of Interest: Director of the Board	☐ open ☑ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: 2007 To: Present	Name and Address of Business: Celsus Therapeutics PLC 24 West 40th Street, 8th Floor, New York, New York 10018	
Business Type: Public Limited Company	Office Held/Nature of Interest: Director of the Board	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

NOT APPLICABLE

(A) SERVED AS CHAIRMAN / CEO

(B) HIMSELF A MEDICAL DOCTOR (BY TRAINING)

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: 5/20/15
Notary Name: Teresa Bair	Notary Registration Number: 02BA6290225
Notary (Notary Must Affix Stamp or Seal) TERESA BROPHY BAIR Notary Public, State of New York Qualified in Erie County My Commission Expires October 7, 2017	Date: 5/20/15

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Jinn Wu	3. Title: N/A

4. Briefly describe the role of this person or entity in the proposed registered organization:

Mr. Wu is a director of Kinex Pharmaceuticals, Inc., which is the sole owner of Kinex Supportive Pharmaceuticals, LLC. Mr. Wu will have no direct role in Kinex Supportive Pharmaceuticals, LLC other than serving on the Kinex Pharmaceuticals, Inc. Board.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☐ Yes ☑ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc.

I have been a member of the Boards of Directors since 2007.

Neither Kinex Pharmaceuticals, Inc. nor I have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax: [redacted]
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
National Taiwan University	Taipei, Taiwan	1967	1971	Bachelor of Science - Pharmacy	1971
National Taiwan Univeraity	Taipei, Taiwan	1973	1975	MS - Pharmaceutical Chemistry	1975
The Ohio State University	281 W. Lane Avenue Columbus, Ohio 43210	1975	1979	PhD	1979

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Name of Employer:
Type of Business:

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: 2007	Name and Address of Business: Kinex Pharmaceuticals, Inc. 701 Ellicott Street, Buffalo, New York 14203	
To: Present		
Business Type: Delaware Corporation	Office Held/Nature of Interest: Director	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

[redacted]

From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: May-19-2015
Notary Name: Christine B. Micale	Notary Registration Number: 2184314
Notary (Notary Must Affix Stamp or Seal) CHRISTINE B. MICALE Notary Public of New Jersey No. 2184314 Commission Expires Nov. 28, 2015	Date: May 19, 2015

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticlals, Inc.

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Charles E. Lannon

3. Title: N/A

4. Briefly describe the role of this person or entity in the proposed registered organization:

Mr. Lannon is a director of Kinex Pharmaceuticals, Inc., which is the sole owner of Kinex Supportive Pharmaceuticals, LLC. Mr. Lannon will have no direct role in Kinex Supportive Pharmaceuticals, LLC other than serving on the Kinex Pharmaceuticals, LLC Board.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☐ Yes ☑ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc.

Currently a member of the Board of Directors.

Neither Kinex Pharmaceuticals, Inc. nor I have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
Canisius College	2001 Main Street Buffalo, NY 14208	1966	1970	Bachelor of Arts	May 1970

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Reason For Departure:
Name of Employer:
Type of Business:

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ **Yes** ☐ **No**

From: 1995	Name and Address of Business: Sovran Self Storage Inc. 6467 Main Street, Buffalo, New York 14221	
To: present		
Business Type: storage units	Office Held/Nature of Interest: Board of Directors	☑ **open** ☐ **closed** ☐ **proposed**
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: 2013 To: Present	Name and Address of Business: Buckingham Properties, LLC 259 Alexander Street, Rochester, New York 14607	
Business Type: Real Estate Investment Trust	Office Held/Nature of Interest: Lead Independent Director	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To: Present	Name and Address of Business: Kinex Pharmaceuticals, Inc. 701 Ellicott Street, Buffalo, New York 14203	
Business Type: pharmaceutical company	Office Held/Nature of Interest: Board of Directors	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: May 19, 2015
Notary Name: Lea A. Herald	Notary Registration Number: 01HE6056705
Notary (Notary Must Affix Stamp or Seal) Lea A. Herald LEA A. HERALD Notary Public, State of New York Qualified in Erie County My Commission Expires March 26, 20 19	Date: May 19, 2015

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Gerald J. Fetterly

3. Title: CEO

4. Briefly describe the role of this person or entity in the proposed registered organization:

The role of Kinex Supportive Pharmaceuticals, LLC. includes being focused on producing pharmaceutical products to help patients manage the pain and suffering from their underlying disease. My role as CEO is to ensure that the entity executes this vision that meets first and foremost the needs of patients, as well as complies with the New York State Department of Health Regulations.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ Yes ☐ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc.

I am currently the Vice President of Clinical and Pharmacology and Regulatory Affairs since January 2015.

Neither Kinex Pharmaceuticals, Inc. nor I have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
School of Pharmacy State University of New York at Buffalo	270 Kapoor Hall Buffalo, New York 14214	09/1994	05/2000	Doctor of Philosophy, Pharmaceutics	May 2000
School of Pharmacy State University of New York at Buffalo	270 Kapoor Hall Buffalo, New York 14214	09/1994	05/1996	Masters' of Science, Pharmaceutics	May 1996
State University of New York at Buffalo	12 Capen Hall Buffalo, New York 14260	09/1990	05/1994	Bachelor of Arts, Chemistry	May 1994

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Name of Employer: State University of New York at Buffalo

Type of Business: University

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address: 12 Capen Hall		
City: Buffalo	State: New York	Zip Code: 14260
Starting Date of Employment: August 2012	Ending Date of Employment: present	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities: Assistant Professor, Department of Pharmaceutical Sciences		
Reason For Departure: n/a		

[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

[redacted]

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: January 2015	Name and Address of Business:	
To: Present	Kinex Pharmaceuticals, Inc. 701 Ellicott Street, Buffalo, New York 14203	
Business Type: pharmaceutical company	Office Held/Nature of Interest: Vice President	☑ open ☐ closed ☐ proposed

Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature: Gerald Fetherty	Date: 5/19/15
Notary Name: Teresa Bair	Notary Registration Number: 02BA6290225
Notary (Notary Must Affix Stamp or Seal)	Date: 5-19-15

TERESA BROPHY BAIR
Notary Public, State of New York
Qualified in Erie County
My Commission Expires October 7, 2017

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Jody Miller	3. Title: Director of Trade and Distribution

4. Briefly describe the role of this person or entity in the proposed registered organization:

Member - Board of Directors
Director of Trade and Distribution
Jody Miller will be responsible for developing and operationalizing the distribution system for Kinex Supportive. This includes responsibility for Transportation, Dispensary operations, Patient Experience and Provider communications.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ **Yes** ☐ **No**

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☐ **Yes** ☑ **No**

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ **Yes** ☑ **No**

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
Canisius College	2001 Main Street Buffalo, NY 14208	1992	1995	M.B.A	1995
Texas State University	601 University Drive San Marcos, TX 78666	1986	1987	B.H.A	1987
University of Texas at San Antonio	1 UTSA Circle San Antonio, TX 78249	1984	1986		
St. Philip's College	1801 Martin Luther King Dr. San Antonio, TX 78203	1982	1983	A.A.S	1983
Herkimer County Community College	100 Reservoir Road Herkimer, NY 13350	1980	1982	A.A.S	1982

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date
Georgia Nursing Home Administration	3551	214 State Capitol Atlanta, GA 30334	12/1989	12/1991

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Redacted pursuant to N.Y. Public Officers Law, Art.6

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ **Yes** ☐ **No**

[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: 2010 To: 2013	Name and Address of Business: Specialty Pharmacy Management LLC. DBA Reliance Rx 45 Earhart Drive Suite 110, Amherst, NY 14221	
Business Type: LLC	Office Held/Nature of Interest: Member	☐ open ☑ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: 2002 To: Present	Name and Address of Business: Medequities Holdings 832 Creekside Drive, Tonawanda, NY 14150	
Business Type: LLC	Office Held/Nature of Interest: Member	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: 2011 To: Present	Name and Address of Business: Infusion Access One Seneca Tower 2820A, Buffalo, NY 14203	
Business Type: LLC	Office Held/Nature of Interest: Member	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

- CEO- Reliance Rx- A NYS licensed Specialty Pharmacy
- Member of 5 Corp Boards
- 30 years as a Healthcare Executive in various institutions
- Consultant to numerous Pharmaceutical Firms
- Nationally recognized speaker on Topics of Drug Distribution in the US

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: 5/27/15
Notary Name: Christian J Henrich	Notary Registration Number: 02HE6110323
Notary (Notary Must Affix Stamp or Seal) CHRISTIAN J. HENRICH Notary Public, State of New York Qualified in Erie County My Commission Expires 05/24/2016	Date: 05/27/15

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Stephen A. Panaro, Ph.D

3. Title: Cheif Executive Officer

4. Briefly describe the role of this person or entity in the proposed registered organization:

As Chief Executive Officer of Kinex Supportive Pharmaceuticals, Dr. Panaro will be responsible for general business and operations oversight.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ Yes ☐ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

[redacted]

None of the above named companies nor Dr. Panaro have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
State University of New York at Buffalo	12 Capen Hall Amherst, New York 14260	1995	2001	Ph.D.	2001
Canisius College	2001 Main Street Buffalo, NY 14208	1990	1995	Bachelor of Science - Chemistry	1995

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Redacted pursuant to N.Y. Public Officers Law, Art.6

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ **Yes** ☐ **No**

[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

[redacted]

From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: 22 MAY 2015
Notary Name: Marie D Lelek	Notary Registration Number: 01LE6097202
Notary (Notary Must Affix Stamp or Seal)	Date:

MARIE D. LELEK
Notary Public - State of New York
No. 01LE6097202
Qualified in Erie County
My Commission Expires Aug 18, 2015

Stephen A. Panaro, Ph.D.

[redacted]
spanaro@qdpharma.com (e-mail)

Executive Summary: Stephen A. Panaro, has over 15 years of experience in the Pharmaceutical Industry. His experience spans from drug discovery and API synthesis, to large-scale commercial production of finished products across many different dosage forms and packaging configurations. Throughout his carrier, Steve has overseen personnel in Nanotechnology, Quality Control (QC) Chemistry, QC Microbiology, Customer Service, Project Management, and Production, to name a few. Currently he is the [redacted] and [redacted] of [redacted], a wholly owned subsidiary of Kinex Pharmaceuticals and a premier company for contract manufacturing of pharmaceutical Rx, OTC and personal care products

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Employment History:

Redacted pursuant to N.Y. Public Officers Law, Art. 6

Redacted pursuant to N.Y. Public Officers Law, Art.6

Education:

Ph.D. 2001, Synthetic Organic Chemistry, State University of New York at Buffalo, Buffalo, New York.
B.S. 1995, Chemistry, Canisius College, Buffalo, New York.

Other Skills:

-Proficient in SAP and Documentum
-Hazmat Certified
-Experienced in 'Lean Manufacturing' techniques

Publications:

Davies, H. M. L.; Panaro, S. A. Effect of Rhodium Carbenoid Structure on Cyclopropanation Chemoselectivity. *Tetrahedron* **2000**, *56*, 4871-4880.

Davies, H. M. L.; Hansen, T.; Hopper, D. W.; Panaro, S. A. Highly Regio-, Diastereo-, and Enantioselective C-H Insertions of Methyl Aryldiazoacetates into Cyclic *n*-Boc-Protected Amines. Asymmetric Synthesis of Novel C_2-Symmetric Amines and *threo*-Methylphenidate. *J. Am. Chem. Soc.* **1999**, *121*, 6509-6510.

Davies, H. M. L.; Panaro, S. A. Novel Dirhodium Tetraprolinate Catalysts Containing Bridging Prolinate Ligands for Asymmetric Carbenoid Reactions. *Tetrahedron Lett.* **1999**, *40*, 5287-5290.

NEW YORK STATE | Department of Health

Medical Marijuana Program
Application for Registration as a Registered Organization

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name:

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name:	3. Title:

4. Briefly describe the role of this person or entity in the proposed registered organization:

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ Yes ☐ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

[redacted]

[redacted]

No Violations

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]		9. Fax: [redacted]	
10. Email: [redacted]			
11. Residence Address: [redacted]			
12. City: [redacted]		13. State: [redacted]	14. ZIP Code: [redacted]

15. Formal Education See Attached		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: 2010	Name and Address of Business: 1(342 main St	
To: Present	Clarence NY 14031	
Business Type: Pharmaceutical	Office Held/Nature of Interest:	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

NEW YORK STATE | Department of Health

Medical Marijuana Program
Application for Registration as a Registered Organization

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Robert F. Keem

3. Title: Director of Manufacturing

4. Briefly describe the role of this person or entity in the proposed registered organization:

As Director of Manufacturing Quality, Mr. Keem will be responsible for all quality system oversight to ensure all regulatory needs are met.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ Yes ☐ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Kinex Pharmaceuticals, Inc. - Vice President of Quality Systems.

[redacted]

Neither Kinex Pharmaceuticals, Inc. [redacted] nor Mr. Keem have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
Buffalo State College	1300 Elmwood Avenue Buffalo, New York 14222	1993	1998	M.A Analytical Chemistry	May 1998
Buffalo State College	1300 Elmwood Avenue Buffalo, New York 14222	1985	1988	B.S. Chemistry	May 1988

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Appendix A:

Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Redacted pursuant to N.Y. Public Officers Law, Art.6

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: April 2015	Name and Address of Business: Kinex Pharmaceuticals, Inc. 701 Ellicott Street, Buffalo, New York 14202	
To: Present		
Business Type: Delaware Corporation	Office Held/Nature of Interest: Vice President of Quality Systems	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature: Robert F Keem	Date: May 22 2015
Notary Name: Marie D. Lelek	Notary Registration Number: 01LE6097202
Notary (Notary Must Affix Stamp or Seal)	Date:

MARIE D. LELEK
Notary Public - State of New York
No. 01LE6097202
Qualified in Erie County
My Commission Expires Aug 18, 2015

ROBERT F. KEEM

SUMMARY

- Effective leader in organization and proficient in managing multiple personnel levels.
- Team player, work well with management, customers, suppliers and operation personnel.
- Excellent communication and problem solving skills within department and in multidisciplinary environment.
- Led productivity projects to reduce cost and improve efficiency
- 15+ years of experience in Quality Assurance and Validation.
- Investigation and resolution for deviations/variances and CAPA closure.
- Experience in pharmaceutical, medical device and biotech production environment.
- Willing to travel.

Quality Assurance proficiencies include the following subject areas:

- Trained and led team members on Quality Management System policies and procedures.
- Proficient in execution of compliance to ISO13485 and cGMPs (820)
- Trained auditor – internal, external and site host
- Investigation and root cause analysis
- Metric development, establishing appropriate goal, measurement intervals, and use in management reviews
- Perform gap analysis and implementation of quality management systems
- Developing supplier management programs based on risk
- Developing new capabilities within organization (e.g., stability program)

Validation proficiencies include the following subject areas:

- Proficient in generating and executing of all validation documents, including Validation Plan, Gap Analysis, Remediation Plan, URS, FRS, FAT, PFMEA, Risk Assessment, Design Specifications, IQ, OQ, and PQ Test Protocols, Traceability Matrices, Test Method Validation, Standard Operating Procedures (SOPs), and Validation Summary Reports.
- Ensured project documentation complied with internal policies and procedures, and external regulations.
- Proficient in equipment, assay and process validation

SKILLS

Life Sciences:	ISO Quality System Regulation, FDA Quality System Regulation, Validation Life Cycle Methodologies, cGMP/GLP Audits, Gap Analysis, SOP Development, FDA Compliance for 21 CFR Part 11, 58, 210, 211and 820
Hardware:	HPLC, UPLC, GC, various laboratory instruments
Software:	Microsoft applications (Microsoft Office, Microsoft Windows, etc.), Trackwise, Agile, Compliance Wire

Robert F. Keem
[redacted]

- Oversee multiple continuous improvement projects including support to other sites for updating QMS policies, and procedures
- Collaboration with manufacturing, R&D, Technical Services and Business teams to support corporate goals and objectives for New Product Introductions and improvement of existing products through voice of customer
- Key member of cross functional teams for trouble shooting processes, formulations and new product introduction (PFMEA,)
- Integral member of compliance audits, customer audits/visit, internal and external presentations
- Support supplier program: develop risk tools to be utilized for supplier audits, material review board, raw material characterization and assay development (including facilitating the use of outside laboratory as needed)
- Policy and procedure writing including implementation of Risk Management Policies at multiple sites
- Team member for global harmonization practices including assay harmonization
- Utilize Six Sigma tools (FMEA, RCA, Lean, 5S) – Lean and Green Belt training
- Internal Auditor Training
- Supplier Qualification Training by PDA
- Executive coaching to support career development for succession planning and communication strategy across levels

[redacted]

[redacted]

- [redacted]
- American Institute of Chemists Award for outstanding academic performance
- Noel Simmon Award for outstanding performance in Biochemistry

EXHIBITS

- Hejmanowski LB, **Keem RF**, Adams MH, Longsteth J, and Wilton JH. Determination of Free Oxaprozin Plasma Concentrations by Ultrafiltration. American Association of Pharmaceutical Scientist Orlando Florida, October 1993.

- Hejmanowski LB, **Keem RF**, Doell JM, and Wilton JH. Determination of Unchanged Hydralazine in Human Whole Blood. American Association of Pharmaceutical Scientists Boston, Massachusetts, October 1997 Chemistry

- **Keem RF**, Godwin, Fike, Gorfien and Price. Analysis of Factors Affecting Cell Growth and Protein Expression in Eukaryotic Cell Culture Systems. American Chemical Society National Meeting, Boston, Massachusetts, August 1998 Chemistry

- **Keem RF,** Analysis of Cholesterol in Mammalian Cell Culture Products and Supplements, American Association of Pharmaceuticals Scientists, Indiana October 2000

EDUCATION

B.S. Buffalo State College, State University of New York, Chemistry
M.A. Buffalo State College, State University of New York, Analytical Chemistry

References furnished upon request

Robert F. Keem
[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: L. Wayne Schultz

3. Title: Director of Lab Production

4. Briefly describe the role of this person or entity in the proposed registered organization:

As Director of Laboratory and Device Production, Dr; Schultz will be involved with all aspects of quality control; including all routine and non-routine testing to ensure product integrity.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ Yes ☐ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☑ Yes ☐ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

[redacted]

Neither [redacted] nor I have been found to have violated any laws or regulations by a governmental agency.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
Cornell University	Ithaca, New York 14853	1992	1995	Ph.D. Biophysical Chemistry	May 1995
Cornell University	Ithaca, New York 14853	1990	1992	M.S. Analytical Science	May 1992
College of Wooster	1189 Beall Avenue Wooster, Ohio 44691	1986	1990	B.A Chemistry	May 1990

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

[redacted]

Name of Employer: State University of New York at Buffalo		
Type of Business: educational institution		
Street Address: Main Street and Kenmore Avenue		
City: Buffalo	State: New York	Zip Code: 14214
Starting Date of Employment: 2001	Ending Date of Employment: 2015	
Name of Supervisor for Reference: [redacted]	Supervisor Phone Number: [redacted]	
Position/Responsibilities: Research Assistant Professor, Department of Structural Biology		
Reason For Departure: [redacted]		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☐ **Yes** ☐ **No**

From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐ **open** ☐ **closed** ☐ **proposed**
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: To:	Name and Address of Business:	
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature: Leonard W. Schultz	Date: MAY 22, 2015
Notary Name: Marie D. Lelek	Notary Registration Number: 01LE6097202
Notary (Notary Must Affix Stamp or Seal)	Date: May 22 2015 MARIE D. LELEK Notary Public - State of New York No. 01LE6097202 Qualified in Erie County My Commission Expires Aug 18, 20 15

Leonard Wayne Schultz, Ph.D.

[redacted]

[redacted]

A highly trained, multidisciplinary project team leader with experience in the fields of chemistry, biochemistry, molecular biology, infectious disease, structural biology, and drug design/discovery. Successful track record of peer reviewed publications (30), invited lectures (15), and government research funding (>$7.5M). An entrepreneurial minded scientist with tech startup, business development, GMP manufacturing, and sales experience.

EXPERIENCE

[redacted]

EDUCATION

Cornell University, Ithaca, NY—Ph.D. Biophysical Chemistry 1995
Thesis Title: *Structural Studies of Immunophilins and Their Complexes*

Cornell University, Ithaca, NY— M.S. Analytical Chemistry 1992

College of Wooster, Wooster, OH—B.A. Chemistry 1990

SPECIFIC SCIENTIFIC EXPERIENCE

Molecular Biology, Cloning, Fermentation, Protein expression and purification, Protein crystallization, X-ray Crystallography, Fluorometry, Small-angle X-ray scattering, UV-vis and IR spectroscopy, Biochemical assay, SPR, calorimetry, ELISA, Western blotting.

AWARDS and HONORS

Semi-Finalist 43North Business Plan Competition	2014
Western New York Healthcare 50	2012
NIH Postdoctoral Fellowship, University of Wisconsin, Madison	1996-1999
Cover illustration, *Bioorg. Med. Chem. Lett.*	1998
NIH Biotechnology Training Grant Fellow, Cornell University	1991-1994
ACA Pauling Prize for Poster Presentation	1994
DuPont Outstanding Teaching Assistant Award, Cornell University	1991
Phi Beta Kappa	1990
Sigma Xi	1990
Honors Thesis/Major, College of Wooster	1990

PUBLICATIONS

30. Umland, T.C., Schultz, L.W., and Russo, T.A., Re-evaluating the approach of drug target discovery in multidrug-resistant Gram- negative bacilli. Future Microbiol. 2014; 9(10): 1113-6. Doi: 10.2217/fmb.14.72.

29. Patel, D., Schultz, L.W. and Umland, T.C., Influenza A polymerase subunit PB2 possesses overlapping binding sites for polymerase subunit PB1 and human MAVS proteins. Virus Res. 2012 Dec 12. pii: S0168-1702(12)00465-0. doi: 10.1016/j.virusres.2012.12.003.

28. Umland, T.C., Schultz, L.W., Macdonald, U., Beanan, J.M., Olson, R. and Russo, T.A., In vivo-validated essential genes identified in Acinetobacter baumannii by using human ascites overlap poorly with essential genes detected on laboratory media. MBio. Aug 31;**3(4)** (2012) pii: e00113-12. doi: 10.1128/mBio.00113-12. PMID: 22911967.

27. Russo T.A., Luke N.R., Beanan J.M., Olson R., Sauberan S.L., MacDonald U., Schultz L.W., Umland T.C., Campagnari A.A.,The K1 capsular polysaccharide of Acinetobacter baumannii strain 307-0294 is a major virulence factor. Infect Immun., **78**(9):3993-4000 (2010).

26. Miknis Z.J., Donaldson E.F., Umland T.C., Rimmer R.A., Baric R.S., Schultz L.W., SARS-CoV nsp9 Dimerization is Essential for Efficient Viral Growth. J. Virology, **83**, 3007-3018 (2009).

25. Russo, T.A., MacDonald, U., Beanan, J.M., Olson, R., MacDonald, I., Schultz, L.W., and Umland T.C., Penicillin binding protein 7/8 contributes to the survival of Acinetobacter baumannii in vitro and in vivo. J. Infect. Dis., **199**, 513-521 (2009).

24. Pletnev, V., Huether, R., Habeggar, L., Schultz, L.W., Duax, W. Rational proteomics of PKD1. I. Modeling the three dimensional structure and ligand specificity of the C-lectin binding domain of Polycystin-1, J. Mol. Model., **13**, 891-896 (2007).

23. Brucz, K., Miknis, Z., Schultz, L. W., and Umland, T., Expression and Purification of Recombinant Severe Acute Respiratory Syndrome Coronavirus Non-structural Protein 1, Prot. Exp. Purif., **52**, 249-257 (2007).

22. Schultz, L. W., Cegielski, M., Liu, L. and Hastings, J. W., Crystal Structure of a pH-regulated Luciferase Catalyzing the Bioluminescent Oxidation of an Open Tetrapyrrole, Proc. Natl. Acad. Sci., **102**, 1378-1383 (2005).

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Book Chapters

Liu, L., Schultz, L. W. and Hastings, J. W. (2005) pH regulation of luciferase activity in dinoflagellates involves a novel enzymatic mechanism. In Bioluminescence & Chemiluminescence: (A. Tsuji, M. Maeda, L.J. Kricka, and P. E. Stanley, Eds.), World Scientific Publ., London.

Patents Held

Raines, R.T.; Leland, P.L.; Schultz, L.W., Engineered Cytotoxic Ribonuclease A, US Patent 5,840,296 (2000).

PROFESSIONAL MEMBERSHIPS AND ACTIVITIES:

Session chair, SAXS, Pittsburgh Diffraction Conference, Buffalo, NY	October, 2007
Session organizer, 32nd Annual Meeting of the American Society for Photobiology Seattle, WA	July, 2004
Chair, Buffalo-Hamilton-Toronto Crystallography Symposium, Hamilton, ON	November, 2001
Session chair, Phasing Methods Pittsburgh Diffraction Conference, Pittsburgh, PA	October, 2000
Member, American Crystallographic Association	1991-present
Member, American Association for the Advancement of Science	1993-present

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmaceuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Christopher W. Kerr, MD

3. Title: Medical Director

4. Briefly describe the role of this person or entity in the proposed registered organization:

As Medical Director, Dr. Kerr will ensure compliance in all matters pertaining to clinical safety, regulations and clinical guidelines. Dr. Kerr will also interface with authorized clinical prescribers and serve as a resource regarding palliative, symptom-based management. The Medical Director will provide key insights and guidance into numerous areas of the organization. He will serve a public role as an advocate for patient access where appropriate.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ Yes ☐ No

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☐ Yes ☑ No

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
University of Rochester	300 Wilson Boulevard Rochester, NY 14627	1995	1998	Completed Internal Medicine Residency	N/A
Medical College of Ohio	3000 Arlington Avenue, #1192 Toledo, Ohio 43614	1991	1995	M.D. - Medical Doctor	June 1995
Ohio State University	250 University Hall 230 N Oval Mall Columbus, Ohio 43210	1987	1991	Ph.D., Neurobiology	June 1991
Kent State University	161 Schwartz Center P.O. Box 5190 Kent, Ohio 44242	1986	1987	B.A. - Psychology	June 1987

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date
Medicine	208041	NYS Education Department	08/27/1997	09/30/2016

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

[redacted]

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

[redacted]

Name of Employer: State University of New York at Buffalo		
Type of Business: Educational Institution		
Street Address: Main Street and Kenmore Avenue		
City: Buffalo	State: New York	Zip Code: 14214
Starting Date of Employment: 2003	Ending Date of Employment: present	
Name of Supervisor for Reference: [redacted]	Supervisor Phone Number: [redacted]	
Position/Responsibilities: Core Faculty, Division of Palliative Medicine (2011 - present) Clinical Assistant Professor, Department of Medicine (2003 - present)		
Reason For Departure: N/A		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☑ Yes ☐ No

From: 2012	Name and Address of Business: Lothlorien Therapeutic Riding Center, Inc. 15 Reiter Road, East Aurora, New York 14052	
To: Present		
Business Type: corporation	Office Held/Nature of Interest: Board President	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From: 2013 To: Present	Name and Address of Business: Mental Health Association of Erie County 999 Delaware Avenue, Buffalo, New York 14209	
Business Type: not-for-profit	Office Held/Nature of Interest: Board Member	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: 2013 To: Present	Name and Address of Business: St. Mary's School for the Deaf 2253 Main Street, Buffalo, New York 14214	
Business Type: educational institution	Office Held/Nature of Interest: Medical Director	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From: 1999 To: Present	Name and Address of Business: Providence Farm 502 Jewett-Holmwood Road, East Aurora, New York 14052	
Business Type: farm	Office Held/Nature of Interest: Owner/Operator	☑ open ☐ closed ☐ proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: 5/28/2015
Notary Name: Helene S. Catalano	Notary Registration Number: 01CA4974632
Notary (Notary Must Affix Stamp or Seal) HELENE S. CATALANO Notary Public, New York State Reg. No. 01CA4974632 Qualified in Erie County Commission Expires November 19, 2018	Date: 05/28/15

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Appendix A **must** be completed for all board members, officers, managers, owners, partners, principal stakeholders, directors, and members. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity, going back to the level of ownership by a natural person. **An Organizational Chart documenting your organizational structure must be included with this application.**

1. Business Name: Kinex Supportive Pharmecuticals, LLC

This is the name that was entered in Section A of the Application for Registration as a Registered Organization.

2. Name: Shane Hutto	3. Title: Head Grower

4. Briefly describe the role of this person or entity in the proposed registered organization:

Mr. Hutto will not be an employee or director of Kinex Supportive Pharmaceuticals, LLC (KS). Mr. Hutto's involvement with KS is limited to his management and ownership of Horticultural Solutions LTD, which is an independent contractor of KS and will be the company responsible for growing the medical marijuana.

5. Will this person or entity come into contact with medical marijuana or medical marijuana products?
☑ **Yes** ☐ **No**

Any managers who may come in contact with or handle medical marijuana, including medical marijuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee. Criminal history background checks must be done through Identogo at http://www.identogo.com/FP/NewYork.aspx using the ORI number NY0412500 and the Fingerprint Reason "Control Substance License."

6. Has this person or entity held any position of management or ownership during the preceding ten years of a 10% or greater interest in any other business which manufactured or distributed drugs? ☐ **Yes** ☑ **No**

If the answer to this question is yes, provide the name of the business, a statement defining the position of management or ownership held in such business, and any finding of violations of law or regulation by a governmental agency against the business or person or entity.

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

7. Has this person or entity been convicted of a felony or had any type of registration or license suspended or revoked in any administrative or judicial proceeding?
☐ Yes ☑ No

If the answer to either of these questions is "Yes," a statement explaining the circumstances of the felony, suspension or revocation must be provided below.

8. Phone: [redacted]	9. Fax:
10. Email: [redacted]	
11. Residence Address: [redacted]	
12. City: [redacted]	13. State: [redacted] 14. ZIP Code: [redacted]

15. Formal Education		Dates Attended		Degree	
Institution	Address	From	To	Degree Received	Date Received
Oklahoma State University	356 Ag. Hall Stillwater, OK 74074	2002	2008	BS - Horticulture	May 2008
Oklahoma State University	356 Ag. Hall Stillwater, OK 74074	2008	2011	MSc - Horticulture	Course 02/201

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

16. Licenses Held: List any and all licenses issued by a governmental or other regulatory entity.

Type of Professional License	License Number	Institution Granting License (Mailing Address, Phone, Email)	Effective Date	Expiration Date

17. Employment History for the Past 10 Years: Start with MOST RECENT employment and include employment during the last 10 years. Attach additional copies of page 3, if necessary.

Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		
Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

Type of Business:		
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		
Name of Employer:	Type of Business:	
Street Address:		
City:	State:	Zip Code:
Starting Date of Employment:	Ending Date of Employment:	
Name of Supervisor for Reference:	Supervisor Phone Number:	
Position/Responsibilities:		
Reason For Departure:		

18. Offices Held or Ownership Interest in Other Businesses

List any affiliations you have been associated with in the past 10 years. Affiliation, for the purpose of this section, includes serving as either a board member, officer, manager, owner, partner, principal stakeholder, director or member of the organization. Organizations outside of New York State must also be disclosed.

Have you owned or operated a business or had any affiliations with the operations of a business in New York, in the USA, or in other countries? ☐ **Yes** ☐ **No**

From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐ **open** ☐ **closed** ☐ **proposed**
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		
From:	Name and Address of Business:	
To:		
Business Type:	Office Held/Nature of Interest:	☐open ☐closed ☐proposed
Name, Address and Phone Number of Licensing/Regulatory Agency, if applicable:		

Appendix A:
Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members

19. Affirmative Statement of Qualifications

For individuals who have not previously served as a director/officer nor have had managerial experience, please include a statement below explaining how you are qualified to operate the proposed facility. This statement should include, but not be limited to, any relevant community/volunteer background and experience.

I have a track record of innovation as well as successful cultivation experience. My education and experience combine to make me the most qualified cultivator and extractor in the cannabis industry. I have managed my own companies as well as project manager on a global level for 5 years. I consult on projects in 15 states and three countries, with the largest being a 325,000 sq ft greenhouse. I work with the largest most professional companies in the industry to provide the best solutions to any cannabis facility.

20. The undersigned certifies, under penalty of perjury, that the information contained herein or attached hereto is accurate, true, and complete in all material respects.

Signature:	Date: 6/2/15
Notary Name: Lea A. Herald	Notary Registration Number: 01HE6051765
Notary (Notary Must Affix Stamp or Seal) LEA A. HERALD Notary Public, State of New York Qualified in Erie County My Commission Expires March 26, 20 19	Date: 06/02/15

Kinex
Pharmaceuticals

June 1, 2015

New York State Department of Health
Bureau of Narcotic Enforcement
Medical Marijuana Program
150 Broadway
Albany, New York 12204

Re: Michael Murphy – Board Member of Kinex Pharmaceuticals, Inc. ("Kinex")

Dear Sirs:

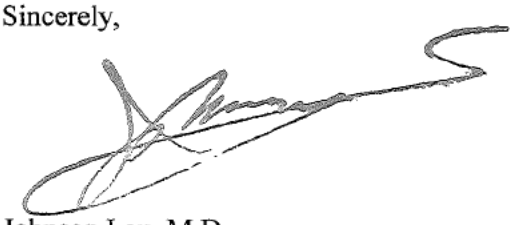
This letter is being provided in connection with the submission of an application (the "Application") by Kinex Supportive Pharmaceuticals, LLC ("Applicant") to the New York State Department of Health for a franchise to manufacture and dispense approved medical marijuana products in New York State. The Applicant is a wholly-owned subsidiary of Kinex. As you know, the Application requires all Board Members of Kinex to submit an affidavit with the Application.

All of Kinex's Board Members except Michael Murphy (http://www.kinexpharma.com/our-company/board-of-directors/) have submitted the required affidavit. Unfortunately for Kinex, Mr. Murphy's law firm, [redacted] will not permit him to continue to serve as Board Member of Kinex in the event that Applicant is awarded a franchise to manufacture and dispense medicinal marijuana (the "Franchise Award").

Therefore, in the event that Applicant receives the Franchise Award, Mr. Murphy will immediately resign from the Board of Kinex. Mr. Murphy has not resigned as of the date of this letter because he is a valuable Board Member of Kinex, and Kinex does not wish to lose his counsel and skills in the event that the Applicant does not receive the Franchise Award.

If you have any questions about the foregoing or require additional comfort that Mr. Murphy will resign in the event Applicant receives the Franchise Award, do not hesitate to call Kinex's corporate counsel Christian J. Henrich, Esq. of Woods Oviatt Gilman, LLP at (716) 249 – 3211.

Sincerely,



Johnson Lau, M.D.
Chairman of the Board
Kinex Pharmaceuticals, Inc.

Office of the Police Chief
City of Lackawanna
James L. Michel Jr.
Police Chief

June 3, 2015

Dr. Howard Zucker
Commissioner
NYS Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Dr. Zucker,

I am pleased to write in support of Kinex Supportive Pharmaceuticals' application to New York State for a license to produce, process and dispense medical marihuana in Erie County. Your plan will produce this medicine at the former Bethlehem Steel Site in the City of Lackawanna.

I have reviewed the security plan for the manufacturing site and have found that it's clear and concise. I look forward to working with Kinex Supportive Pharmaceuticals in the future with any security issues that may arise.

Sincerely,

James Michel
City of Lackawanna
Police Chief

714 RIDGE ROAD · ROOM 109 · LACKAWANNA, NEW YORK 14218 · (716) 827-6499

PHILADELPHIA
INSURANCE COMPANIES

A Member of the Tokio Marine Group

BOND# **PB00464500142**

FINANCIAL GUARANTEE BOND

KNOW ALL MEN BY THESE PRESENTS, that we, **Kinex Supportive Pharmaceuticals, LLC** as Principal, and, **PHILADELPHIA INDEMNITY INSURANCE COMPANY**, a corporation organized under the laws of the State of PENNSYLVANIA, and duly authorized to transact business in the State of New York, as Surety, are held and firmly bound unto the New York State Department of Health, in the penal sum of **Two Million, Dollars ($2,000,000)**, lawful money of the United States, to the payment of which well and truly to be made we hereby bind ourselves and our heirs, administrators, successors, and assigns, jointly and severally, firmly by these presents.

WHEREAS the above bounden Principal has applied to be a Registered Organization in accordance with NY Public Health Law § 3364 and 10 NYCRR 1004.5.

WHEREAS, as part of the application process to be a Registered Organization, the Principal hereby furnishes the referenced bond in accordance with NY Public Health Law § 3365(1)(a)(ii)(B) and 10 NYCRR 1004.5(b)(9).

NOW THEREFORE, if the Principal complies with NY Public Health Law § 3365(1)(a)(ii)(B) and 10 NYCRR 1004.5(b)(9) , then this bond shall be null and void, otherwise to be in full force and effect.

PROVIDED HOWEVER, that this bond is executed by the Surety and accepted by the Obligee subject to the following expressed conditions:

Should the Principal withdraw from the application process and/or not be selected for registration as a Registered Organization, this bond shall be released.

2. Should the Principal fail to show possession or right to use of land, buildings and equipment to carry on the activities for which the registration is sought in accordance with NY Public Health Law § 3365(1)(a)(ii)(B) and 10 NYCRR 1004.5(b)(9), then the Principal's application to be a Registered Organization shall not be granted and this bond shall be released.
3. Neither non-renewal by the Surety, nor failure, nor inability of the Principal to file a replacement bond shall constitute a loss to the Obligee which is recoverable under this bond.
4. Surety's liability under this bond in connection therewith shall not be cumulative and shall in no event exceed the amount as set forth in this bond or in any additions, riders, or endorsements properly issued by the Surety as supplements thereto.
5. No claim, action, suit or proceeding, except as herein set forth, shall be had or maintained against the Surety on this bond unless same be brought or instituted and process served upon the Surety within six months following the expiration of the original term of this bond, or extended term as provided herein.
6. Furthermore, the Surety may cancel this bond and be relieved of further liability for any reason by delivering 30 day written notices to the named Principal and Obligee.

Signed, sealed and dated this **2nd** day of **June**, 20**15**.

Kinex Supportive Pharmaceuticals, LLC

BY _____
Stephen Panaro, Managing Member
(Seal)

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100, Bala Cynwyd, PA 19004

By _____
William M. Chapman, Attorney-In-Fact

THIS BOND MUST BE DRAFTED, SIGNED AND SEAL BY PHILDELPHIA SURETY EMPLOYEES ONLY

ACKNOWLEDGEMENT BY LLC
STATE OF NEW YORK
COUNTY OF Erie

On this 2nd day of June, 2015, before me personally came Stephen Panaro, to me known, who, being by me duly sworn, did depose and say ~~(s)~~he resides in [redacted]; that ~~(s)~~he is the Managing Member of the Kinex Supportive Pharmaceuticals, LLC, the corporation described in and which executed the above instrument; that ~~(s)~~he knew the seal of such corporation; that the seal so affixed to said instrument was such corporate seal; and that it was so affixed by order of the Board of Directors of the corporation; and that ~~(s)~~he signed his/~~her~~ name thereto by like order.

Marie D. Lelek
Notary Public

MARIE D. LELEK
Notary Public - State of New York
No. 01LE6097202
Qualified in Erie County
My Commission Expires Aug 18, 2015

PHILADELPHIA INDEMNITY INSURANCE COMPANY
231 St. Asaph's Rd., Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint **William Chapman, Jade Henderson, Chad Teague, Stephanie Pawlak and Zach Hill**, its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.00**.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY at a meeting duly called the 1st day of July, 2011.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company to: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and biding upon the Company in the future with the respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 10TH DAY OF JUNE 2013.

(Seal)

Robert D. O'Leary Jr., President & CEO
Philadelphia Indemnity Insurance Company

On this 10th day of June 2013, before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Kimberly A. Kessler, Notary Public
Lower Merion Twp. Montgomery County
My Commission Expires Dec. 18, 2016
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

Notary Public: _____

residing at: [redacted]

(Notary Seal)

My commission expires: December 18, 2016

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do herby certify that the foregoing resolution of the Board of Directors and this Power of Attorney issued pursuant thereto on this 10TH day of June 2013 true and correct and are still in full force and effect. I do further certify that Robert D. O'Leary Jr., who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY,

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this **2nd** day of **June, 2015**.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus

Admitted Assets	As of December 31, 2013	2012
Bonds, at statement value (market value $5,687,336,332 and $5,554,079,175)	$ 5,603,006,398	$ 5,148,801,438
Common stocks, at fair value (cost $3,594,300 and $6,228,900)	3,594,300	6,228,900
Other invested assets	26,678,075	-
Cash, cash equivalents and short-term investments	2,440,431	81,992,739
Receivable for sold securities	-	126,883
Cash and invested assets	5,635,719,204	5,237,149,960
Premiums receivable, agents' balances and other receivables	626,336,508	527,610,866
Reinsurance receivable on paid losses	26,175,896	28,657,053
Accrued investment income	61,467,019	57,334,128
Receivable from affiliates	2,947,843	7,831,835
Net deferred tax asset	162,476,407	160,215,214
Federal income taxes receivable	10,908,926	28,147,210
Guaranty funds receivable	29,240	323,335
Total admitted assets	$ 6,526,061,043	$ 6,047,269,601

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 2,895,803,181	$ 2,653,172,627
Unearned premiums	1,164,576,407	1,077,599,587
Reinsurance payable on paid loss and loss adjustment expenses	3,621,130	7,839,717
Ceded reinsurance premiums payable	63,155,239	59,827,255
Commissions payable, contingent commissions and other similar charges	204,448,194	178,129,692
Accrued expenses and other liabilities	31,505,102	29,154,215
Payable to affiliates	4,695,153	5,445,626
Provision for reinsurance	1,322,899	1,397,979
Payable for policyholders' dividends	220,233	-
Payable for purchased securities	-	17,524,284
Total liabilities	$ 4,369,347,538	$ 4,030,090,982
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 359,995 shares issued and outstanding	3,599,950	3,599,950
Surplus:		
Gross paid-in and contributed surplus	386,970,317	386,970,317
Unassigned surplus	1,766,143,238	1,626,608,352
Total surplus	2,153,113,555	2,013,578,669
Total capital and surplus	2,156,713,505	2,017,178,619
Total liabilities and capital and surplus	$ 6,526,061,043	$ 6,047,269,601

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 5th day of June 2014.

Kimberly Kessleski, Notary

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Kimberly A. Kessleski, Notary Public
Lower Merion Twp., Montgomery County
My Commission Expires Dec. 18, 2016

NYS PRODUCER COMPENSATION DISCLOSURE REGULATION 194

IMPORTANT NOTICE FROM FIRST NIAGARA RISK MANAGEMENT:

First Niagara Risk Management (FNRM) represents many insurance companies and these companies often have agreements with FNRM for additional incentive compensation beyond the compensation specific to this proposal. We are an insurance producer domiciled in and licensed by the State of New York. Insurance producers are authorized by their license to confer with insurance purchasers about the benefits, terms and conditions of insurance contracts; to sell insurance; and to obtain insurance for purchasers. The role of the producer in any particular transaction typically involves one or more of these activities.

Compensation will be paid to the producer, based on the insurance contract the producer sells. Depending on the insurer(s) and insurance contract(s) the purchaser selects, compensation will be paid by the insurer(s) selling the insurance contract or by another third party. Such compensation may vary depending on a number of factors, including the insurance contract(s) and the insurer(s) the purchaser selects. In some cases, other factors such as the volume of business a producer provides to an insurer or the profitability of insurance contracts a producer provides to an insurer also may affect compensation.

The insurance purchaser may obtain information about compensation expected to be received by the producer based in whole or in part on the sale of insurance to the purchaser, and (if applicable) compensation expected to be received based in whole or in part on any alternative quotes presented to the purchaser by the producer, by requesting such information from the producer.

AUDITED
FINANCIAL STATEMENTS

KINEX SUPPORTIVE PHARMACEUTICALS, LLC (A LIMITED LIABILITY COMPANY)

FOR THE PERIOD FROM INCEPTION (MAY 13, 2015) THROUGH MAY 31, 2015

KINEX SUPPORTIVE PHARMACEUTICALS, LLC
(A LIMITED LIABILITY COMPANY)
FOR THE PERIOD FROM INCEPTION (MAY 13, 2015) THROUGH MAY 31, 2015

CONTENTS

FreedMaxick CPAs, P.C.

INDEPENDENT AUDITOR'S REPORT

To the Board of Directors
Kinex Supportive Pharmaceuticals, LLC

Report on the Financial Statements

We have audited the accompanying financial statements of Kinex Supportive Pharmaceuticals, LLC which comprise the balance sheet as of May 31, 2015, and the related statements of operations, member's capital, and cash flows for the period from inception (May 13, 2015) through May 31, 2015 and the related notes to the consolidated financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a reasonable basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Kinex Supportive Pharmaceuticals, LLC as of May 31, 2015, and the results of its operations and its cash flows for the period from inception (May 13, 2015) through May 31, 2015 in accordance with accounting principles generally accepted in the United States of America.

Freed Maxick CPAs, P.C.

Buffalo, New York
June 3, 2015

KINEX SUPPORTIVE PHARMACEUTICALS, LLC
(A LIMITED LIABILITY COMPANY)

BALANCE SHEET
May 31, 2015

ASSETS		
Current assets:		
Cash	$	2,000,000
Total current assets		2,000,000
Property and equipment		105,000
	$	2,105,000
LIABILITIES AND MEMBER'S CAPITAL		
Current liabilities:		
Accounts payable and accrued expenses	$	145,816
Total current liabilities		145,816
Member's capital		1,959,184
	$	2,105,000

See accompanying notes.

KINEX SUPPORTIVE PHARMACEUTICALS, LLC
(A LIMITED LIABILITY COMPANY)

STATEMENT OF OPERATIONS AND MEMBER'S CAPITAL
From Inception (May 13, 2015) through May 31, 2015

Operating expenses:		
Professional fees	$	40,606
Taxes and licenses		210
Total operating expenses		40,816
Net loss		(40,816)
Member's capital - beginning of period		-
Capital Contribution		2,000,000
Member's capital - end of period	$	1,959,184

See accompanying notes.

KINEX SUPPORTIVE PHARMACEUTICALS, LLC
(A LIMITED LIABILITY COMPANY)
FOR THE PERIOD FROM INCEPTION (MAY 13, 2015) THROUGH MAY 31, 2015

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. NATURE OF OPERATIONS AND PRINCIPAL ACCOUNTING POLICIES

Organization: Kinex Supportive Pharmaceuticals, LLC (a Limited Liability Company) (the Company), was organized on May 13, 2015 and is a wholly owned subsidiary of Kinex Pharmaceuticals, Inc. The Company is in the process of filing an application for the manufacturing and dispensing medical cannabis to certified patients under the NYS Compassionate Care Act for medicinal purposes only.

Concentration of Credit Risk: Financial instruments that potentially subject the Company to credit risk consist of cash accounts in financial institutions. Although certain cash and other investment accounts exceed the federally insured deposit amount, management does not anticipate nonperformance by any of the financial institutions with which it does business.

Property and Equipment: Property and equipment is recorded at cost and is depreciated using the straight-line method over their estimated useful lives. Maintenance and repairs that do not extend the life of assets are charged to expense when incurred.

Construction in Progress amounted to $105,000 as of May 31, 2015 and represents costs incurred for the plan and design of the building the Company plans to build. No depreciation expense was recorded during the period ended May 31, 2015.

Income Taxes: Since the Company is a single member LLC, it is a disregarded entity for tax purposes. Accordingly federal and state tax regulations provide that, in lieu of corporate income taxes, the member includes the Company's items of income, deductions, losses and credits on its respective tax return. There are no material taxable temporary differences that exist as of May 31, 2015.

Start-up costs: Costs incurred in connection with start-up activities are charged to operations as they are incurred.

Related Party Transaction: Included in Accounts Payable is a $15,000 related party payable to the Company's parent company, Kinex Pharmaceuticals, Inc. for expenditures paid on the Company's behalf.

Subsequent Events: These financial statements have not been updated for subsequent events occurring after June 3, 2015 which is the date these financial statements were available to be issued.

NEW YORK STATE | Department of Health

Medical Marijuana Program
Application for Registration as a Registered Organization

Section A: Business Entity Information		
1. Business Name: Kinex Supportive Pharmaceuticals, LLC		
2. Organization Type (choose one): X For-profit □ Non-profit	3. Business Type (choose one): □ Corporation □ Sole Proprietorship □ Limited Partnership □ Other: X Limited Liability Company □ General Partnership	
4. Phone: 716-898-8636	5. Fax:	6. Email:
7. Business Address: 701 Ellicott Street		
8. City: Buffalo	9. State: NY	10. ZIP Code: 14203
11. Mailing Address (if different than Business Address):		
12. City:	13. State:	14. ZIP Code:

Section B: Primary Contact Information		
15. Name: Jody Miller, MBA		16. Title: Chief Operating Officer
17. Phone: 716-440-0192	18. Fax:	19. Email: jmiller@4frontcg.com
20. Mailing Address: One Seneca Tower, Suite 2820A,		
21. City: Buffalo	22. State: NY	23. ZIP Code: 14203

Section C: Proposed Manufacturing Facility Information		
24. Proposed Facility Name: Kinex Supportive Pharmaceuticals Cultivation and Manufacturing Center		
25. Proposed Facility Address: 2303 Hamburg Turnpike		
26. City: Lackawanna	27. State: **NY**	28. ZIP Code: 14218
29. County: Erie	30. Property Status (choose one): □ Owned by the applicant □ Leased by the applicant X Other: See Tab 6, Attachment A., Identification of real property, buildings, and facilities. **If you checked "Other" above, describe the property status in the**	

31. Proposed Hours of Operation:

Monday: 8:00 AM	to 5:00 PM	Friday: 8:00 AM	To 5:00 PM
Tuesday: 8:00 AM	to 5:00 PM	Saturday:	to
Wednesday: 8:00 AM	to 5:00 PM	Sunday:	to
Thursday: 8:00 AM	to 5:00 PM		

An additional entry is included below for applicants who are proposing to use more than one manufacturing facility (responsible for cultivation, harvesting, extraction or other processing, packaging and labeling).

32. Proposed Facility Name: N/A		
33. Proposed Facility Address:		
34. City:	35. State: **NY**	36. ZIP Code:
37. County:	38. Property Status (choose one): □ Owned by the applicant □ Leased by the applicant □ Other: **If you checked "Other" above, describe the property status in the field provided.**	

39. Proposed Hours of Operation:

Monday:	to	Friday:	to
Tuesday:	to	Saturday:	to
Wednesday:	to	Sunday:	to
Thursday:	to		

Section D: Proposed Dispensing Facility #1 Information

40. Proposed Facility Name: Kinex Supportive Pharmaceuticals Dispensary		
41. Proposed Facility Address: 81 Benbro Street		
42. City: Cheektowaga	43. State: **NY**	44. ZIP Code: 14225
45. County: Erie	46. Property Status (choose one): □ Owned by the applicant □ Leased by the applicant X Other: See Tab 6, Attachment A., Identification of real property, buildings, and facilities.	

47. Proposed Hours of Operation:

Monday: 10:00 AM	to 6:00 PM	Friday: 10: 00 AM	To 6:00 PM
Tuesday: 10:00 AM	to 6:00 PM	Saturday:	to
Wednesday: 10:00 AM	to 6:00 PM	Sunday:	to
Thursday: 10:00 AM	to 6:00 PM		

Section E: Proposed Dispensing Facility #2 Information

48. Proposed Facility Name: Kinex Supportive Pharmaceuticals Dispensary		
49. Proposed Facility Address: 135 Corporate Woods		
50. City: Rochester	51. State: **NY**	52. ZIP Code: 14623
53. County: Monroe	54. Property Status (choose one): □ Owned by the applicant □ Leased by the applicant X Other: See Tab 6, Attachment A., Identification of real property, buildings, and facilities.	

55. Proposed Hours of Operation:

Monday: 10:00 AM	to 6:00 PM	Friday: 10:00 AM	to 6:00 PM
Tuesday: 10:00 AM	to 6:00 PM	Saturday:	to
Wednesday: 10:00 AM	to 6:00 PM	Sunday:	to
Thursday: 10:00 AM	to 6:00 PM		

Section F: Proposed Dispensing Facility #3 Information

56. Proposed Facility Name: Kinex Supportive Pharmaceuticals Dispensary

57. Proposed Facility Address: 2320 Court Street

58. City: Syracuse	59. State: **NY**	60. ZIP Code: 13206

61. County: Onondaga

62. Property Status (choose one):
- □ Owned by the applicant
- □ Leased by the applicant
- X Other: See Tab 6, Attachment A., Identification of real property, Buildings, and facilities.

If you checked "Other" above, describe the property status in the field provided.

63. Proposed Hours of Operation:

Monday: 10:00 AM	to 6:00 PM	Friday: 10:00 AM	To 6:00 PM
Tuesday: 10:00 AM	to 6:00 PM	Saturday:	To
Wednesday: 10:00 AM	to 6:00 PM	Sunday:	To
Thursday: 10:00 AM	to 6:00 PM		

Section G: Proposed Dispensing Facility #4 Information

64. Proposed Facility Name: Kinex Supportive Pharmaceuticals Dispensary

65. Proposed Facility Address: 933 Loudon Rd.

66. City: Latham	67. State: **NY**	68. ZIP Code: 12110

69. County: Albany

70. Property Status (choose one):
- □ Owned by the applicant
- □ Leased by the applicant
- X Other: See Tab 6, Attachment A., Identification of real Property , buildings, and facilities.

If you checked "Other" above, describe the property Status in the field provided.

71. Proposed Hours of Operation:

Monday: 10:00 AM	to 6:00 PM	Friday: 10:00 AM	To 6:00 PM
Tuesday: 10:00 AM	to 6:00 PM	Saturday:	to
Wednesday: 10:00 AM	to 6:00 PM	Sunday:	to
Thursday: 10:00 AM	to 6:00 PM		

Section H: Legal Disclosures

72. Has the applicant, any controlling person of the applicant, any manager, any principal stakeholder, any sole proprietor applicant, any general partner of a partnership applicant, any officer or member of the board of directors of a corporate applicant, or corporate general partner had a prior discharge in bankruptcy or been found insolvent in any court action? ☐**Yes** X **No**

If the answer to this question is "Yes," a statement providing details of such bankruptcy or insolvency must be included with this application.

73. Does any controlling person of the applicant, any manager, any principal stakeholder, any sole proprietor applicant, any general partner of a partnership applicant, any officer or member of the board of directors of a corporate applicant, or corporate general partner, or a combination of such persons collectively, maintain a ten percent interest or greater in any firm, association, foundation, trust, partnership, corporation or other entity, and such entity will or may provide goods, leases, or services to the registered organization, the value of which is or would be five hundred dollars or more within any one year?

OR

Does any entity maintain a ten percent interest or greater in the applicant, and such entity will or may provide goods, leases, or services to the registered organization, the value of which is or would be five hundred dollars or more within any one year?

X **Yes** ☐**No**

If the answer to either of these questions is "Yes," a statement with the name and address of the entity together with a description of the goods, leases, or services and the probable or anticipated cost to the registered organization, must be included with this application.

74.

A. Is the applicant a corporate subsidiary or affiliate of another corporation? X **Yes** ☐**No**

If the answer to this question is "Yes," a statement setting forth the name and address of the parent or affiliate, the primary activities of the parent or affiliate, the interest in the applicant held by the parent or affiliate, and the extent to which the parent will be involved in the activities of the applicant, and responsible for the financial and contractual obligations of the subsidiary must be included with this application. The organizational and operational documents of the corporate subsidiary or affiliate must also be submitted, including but not limited to, as applicable: the certificate of incorporation, bylaws, articles of organization, partnership agreement, operating agreement, and all amendments thereto, and other applicable documents and agreements including in relation to the subsidiary or affiliate's financial or contractual obligations with respect to the applicant.

B. Is any owner, partner or member of the applicant not a natural person? X **Yes** ☐**No**

If the answer to this question is "Yes," a statement must be included with this application setting forth the name and address of the entity, the primary activities of the entity, the interest in the applicant held by the entity, and the extent to which the entity will be involved in the activities of the applicant, and responsible for the financial and contractual obligations of the applicant. The organizational and operational documents of the entity must also be submitted, including but not limited to, as applicable: the certificate of incorporation, bylaws, articles of organization, partnership agreement, operating agreement, and all amendments thereto, and other applicable documents and agreements including in relation to the entity's financial or contractual obligations with respect to the applicant, and the identification of all those holding an interest or ownership in the entity and the percentage of interest or ownership held in the entity. If an interest or ownership in the entity is not held by a natural person, the information and documentation requested herein must be provided going back to the level of ownership by a natural person (Principal Stakeholder).

75. Has construction, lease, rental, or purchase of the manufacturing facility been completed? ☐Yes X No

If the answer to this question is "No," a statement indicating the anticipated source and application of the funds to be used in such purchase, lease, rental or construction, as well as anticipated date that construction, lease, rental or purchase will be completed must be included with this application.

See Tab 6, Attachment A., Identification of real property, Buildings, and facilities.

76. Has construction, lease, rental, or purchase of the dispensing facilities been completed? ☐Yes X No

If the answer to this question is "No," a statement indicating the anticipated source and application of the funds to be used in such purchase, lease, rental or construction, as well as anticipated date that construction, lease, rental or purchase will be completed must be included with this application.

See Tab 6, Attachment A., Identification of real property, Buildings, and facilities.

Section I: Required Attachments

Applications received without the required attachments will not be eligible for consideration until the required attachments are received. All such attachments must be postmarked by the Deadline for Submission of Applications.

77. X The applicant has enclosed a non-refundable application fee in the amount of $10,000.
Applications received without the $10,000 application fee will not be considered.

78. X The applicant has enclosed a conditionally refundable registration fee in the amount of $200,000.
Applications received without the $200,000 registration fee will not be considered.
The $200,000 registration fee will be refunded to applicants that are not selected as registered organizations.

79. X The applicant has attached all required statements from Section H: Legal Disclosures, if applicable.

80. X The applicant has attached identification of all real property, buildings, and facilities that will be used in manufacturing and dispensing activities, pursuant to PHL § 3365 and 10 NYCRR § 1004.5(b)(2), and labeled this attachment as "**Attachment A.**"

81. X The applicant has attached identification of all equipment that will be used to carry out the manufacturing, processing, transportation, distributing, sale, and dispensing activities described in the application and operating plan, pursuant to PHL § 3365 and 10 NYCRR § 1004.5(b)(3), and labeled this attachment as "**Attachment B.**"

82. X The applicant has attached copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, showing that the applicant possesses or has the right to use sufficient land, buildings, other premises, and equipment, and contains the language required in 10 NYCRR § 1004.5(b)(9), if applicable, or, in the alternative, the applicant attached proof that it has posted a bond of not less than $2,000,000, pursuant to PHL § 3365 and 10 NYCRR § 1004.5(b)(9), and labeled this attachment as "**Attachment C.**"

83. X The applicant has attached an operating plan that includes a detailed description of the applicant's manufacturing processes, transporting, distributing, sale and dispensing policies or procedures, and contains the components set forth in 10 NYCRR § 1004.5(b)(4), and labeled the operating plan as "**Attachment D – Operating Plan**" with the information clearly labeled and divided into the following sections:

Section 1 - Manufacturing (§ 1004.5(b)(4))
Section 2 - Transport and Distribution (§ 1004.5(b)(4))
Section 3 - Dispensing and Sale (§ 1004.5(b)(4))
Section 4 - Devices (§ 1004.5(b)(4)(i))
Section 5 - Security and Control (§ 1004.5(b)(4)(ii))
Section 6 - Standard Operating Procedure (§ 1004.5(b)(4)(iii))
Section 7 - Quality Assurance Plans (§ 1004.5(b)(4)(iv))
Section 8 - Returns, Complaints, Adverse Events and Recalls (§ 1004.5(b)(4)(v))
Section 9 - Product Quality Assurance (§ 1004.5(b)(4)(vi))
Section 10- Recordkeeping (§ 1004.5(b)(4)(vii))

84. X The applicant has attached copies of the organizational and operational documents of the applicant, pursuant 10 NYCRR § 1004.5(b)(5), which must include the identification of all those holding an interestor ownership in the applicant and the percentage of interest or ownership held, and labeled this attachment as "**Attachment E.**"

85. X "**Appendix A: Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members**" has been completed for each of the board members, officers, managers, owners, partners, principal stakeholders, directors, and any person or entity that is a member of the applicant setting forth the information required in PHL § 3365(1)(a)(iv) and 10 NYCRR § 1004.5(b)(6).

86. X The applicant has attached documentation that the applicant has entered into a labor peace agreement with a bona fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees, pursuant to PHL § 3365(1)(a)(iii) and 10 NYCRR § 1004.5(b)(7), and labeled this attachment as "**Attachment F.**"

87. X The applicant has attached a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application, pursuant to 10 NYCRR § 1004.5(b)(10), and labeled this attachment as "**Attachment G.**"

88. X The applicant has completed **"Appendix B – Architectural Program"** and included the components set forth in 10 NYCRR § 1004.5(b)(11) and -(12).

89. X The applicant has attached the security plan of the applicant's proposed manufacturing and dispensing facilities indicating how the applicant will comply with the requirements of Article 33 of the Public Health Law, 10 NYCRR Part 1004, and any other applicable state or local law, rule, or regulation, and labeled this attachment as "**Attachment H.**"

90. X The applicant has attached the most recent financial statement of the applicant prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis and certified by an independent certified public accountant, in accordance with the requirements of 10 NYCRR § 1004.5(b)(16), and labeled this attachment as "**Attachment I.**"

91. X The applicant has attached a staffing plan for staff to be involved in activities related to the cultivation of marijuana, the manufacturing and/or dispensing of approved medical marijuana products, and/or staff with oversight responsibilities for such activities that includes the requirements set forth in 10 NYCRR § 1004.5(b)(18) of the regulations and labeled this attachment as "**Attachment J.**"

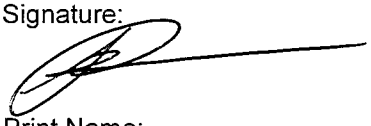
92. X The applicant has attached proof from the local internet service provider(s) that all of the applicant's manufacturing and dispensing facilities are located in an area with internet connectivity and labeled this attachment as "**Attachment K.**" Internet connectivity will be required to support the use of a Seed-to-Sale Solution approved by the Department to record the registered organization's permitted activities.

93. X The applicant has attached a timeline demonstrating the estimated timeframe from growing marijuana to production of a final approved product, and labeled this attachment as "**Attachment L.**"

94. X The applicant has attached a statement and/or documentation showing that the applicant is able to comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the registration, pursuant to 10 NYCRR § 1004.5(b)(8), and labeled this attachment as "**Attachment M.**"

Section J: Attestation and Signature

As the chief executive officer duly authorized by the board of a corporate applicant, or a general partner or owner of a proprietary applicant, I hereby authorize the release of any and all applicant information of a confidential or privileged nature to the Department and its agents. If granted a registration, I hereby agree to ensure the registered organization uses the Seed-to-Sale Solution approved by the Department to record the registered organization's permitted activities. I hereby certify that the information provided in this application, including in any statement or attachments submitted herewith, is truthful and accurate. I understand that any material omissions, material errors, false statements, misrepresentations, or failure to provide any requested information may result in the denial of the application or other action as may be allowed by law.

95. Signature: ▶ 

96. Date Signed: 06/04/2015

97. Print Name: Stephen A. Panaro

The application must include a handwritten signature by the chief executive officer duly authorized by the board of a corporate applicant, or a general partner or owner of a proprietary applicant, and must be notarized.

Notary Name: Marie D. Lelek	Notary Registration Number: 01LE6097202
Notary (Notary Must Affix Stamp or Seal) MARIE D. LELEK Notary Public - State of New York No. 01LE6097202 Qualified in Erie County My Commission Expires Aug 18, 2015	Date: 04 Jun 2015

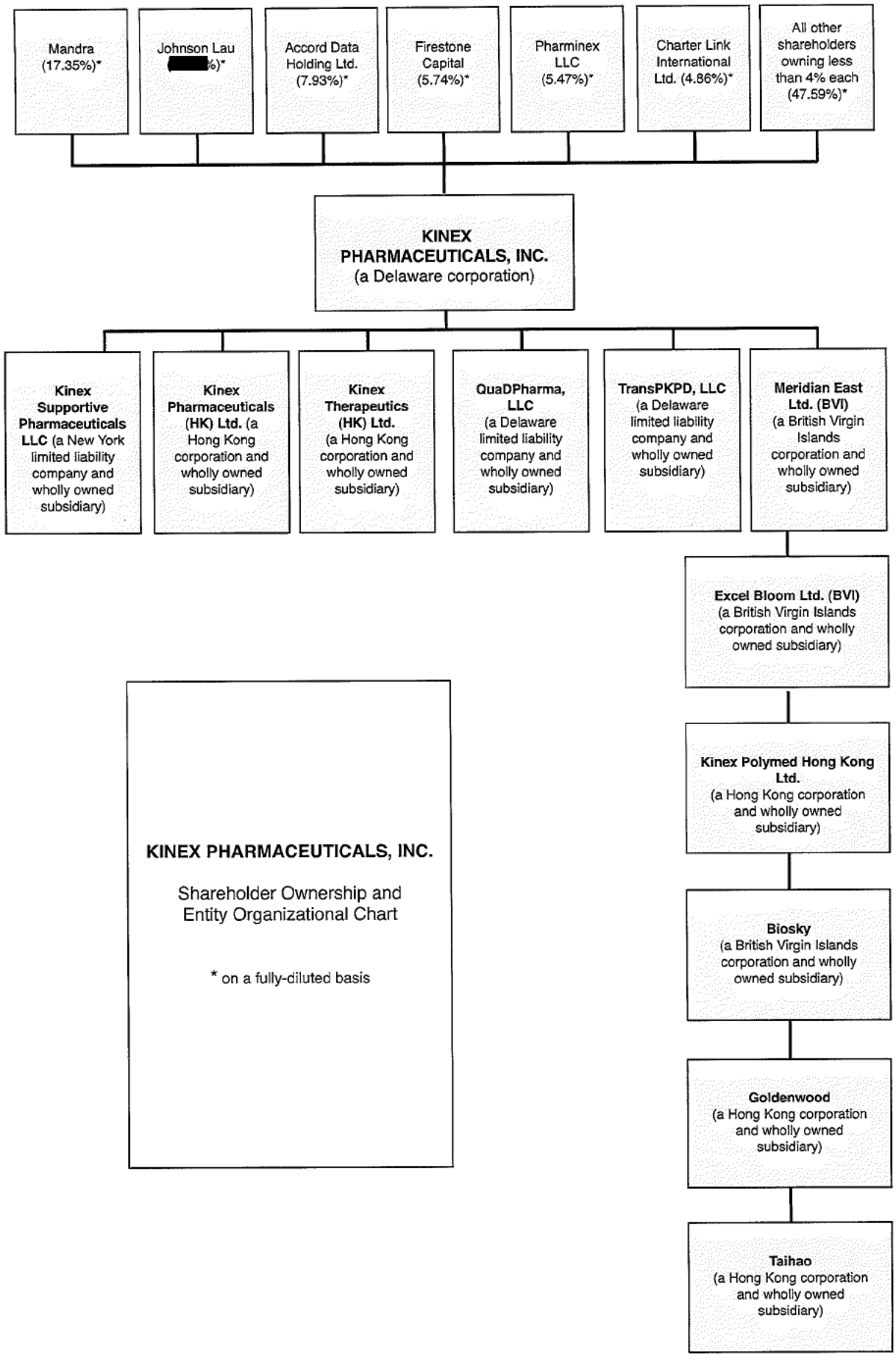
June 1, 2015
Kinex Supportive Pharmaceuticals,

In order to comply with the Compassionate Care Act application, proof of internet access from a local service provider is needed. More specifically, attachment K calls for proof that all applicants' manufacturing and dispensing facilities are located in an area with internet connectivity. For the dispensary location at 933 New Loudon Road Coulumbia Plaza Latham NY, 12110. Verizon has services HSI & Hicap services available in the area [HSI is High Speed Internet (DSL) - up to 3Mb, hicap services – DS1, DS3, Ethernet].

Sincerely,

Robert Dintrone

Robert Dintrone
Design Engineer
Verizon
518-312-5728


Mandra (17.35%)*
Johnson Lau [redacted]%)*
Accord Data Holding Ltd. (7.93%)*
Firestone Capital (5.74%)*
Pharminex LLC (5.47%)*
Charter Link International Ltd. (4.86%)*
All other shareholders owning less than 4% each (47.59%)*
KINEX PHARMACEUTICALS, INC. (a Delaware corporation)
Kinex Supportive Pharmaceuticals LLC (a New York limited liability company and wholly owned subsidiary)
Kinex Pharmaceuticals (HK) Ltd. (a Hong Kong corporation and wholly owned subsidiary)
Kinex Therapeutics (HK) Ltd. (a Hong Kong corporation and wholly owned subsidiary)
QuaDPharma, LLC (a Delaware limited liability company and wholly owned subsidiary)
TransPKPD, LLC (a Delaware limited liability company and wholly owned subsidiary)
Meridian East Ltd. (BVI) (a British Virgin Islands corporation and wholly owned subsidiary)
Excel Bloom Ltd. (BVI) (a British Virgin Islands corporation and wholly owned subsidiary)
Kinex Polymed Hong Kong Ltd. (a Hong Kong corporation and wholly owned subsidiary)
Biosky (a British Virgin Islands corporation and wholly owned subsidiary)
Goldenwood (a Hong Kong corporation and wholly owned subsidiary)
Taihao (a Hong Kong corporation and wholly owned subsidiary)
KINEX PHARMACEUTICALS, INC.
Shareholder Ownership and Entity Organizational Chart
* on a fully-diluted basis

Kinex
Pharmaceuticals

June 2, 2015

New York State Department of Health
Bureau of Narcotic Enforcement
Medical Marijuana Program
150 Broadway
Albany, New York 12204

Re: Table of Organization of Kinex Pharmaceuticals, Inc. ("Kinex") and Kinex Supportive Pharmaceuticals, LLC ("Applicant")

Dear Sirs:

This letter is being provided in connection with the submission of an application (the "Application") by Applicant to the New York State Department of Health for a franchise to manufacture and dispense approved medical marijuana products in New York State. The Applicant is a wholly-owned subsidiary of Kinex.

Kinex (http://www.kinexpharma.com/) is a well-capitalized, global specialty oncology pharmaceutical company focused on the development and commercialization of next generation therapies for cancer diseases and supportive therapies. Kinex is headquartered in Buffalo, New York and originally founded and funded over a decade ago by prominent researchers and businessmen in the Buffalo community. Today, Kinex is a global company with pharmaceutical manufacturing operations located both within New York State, as well as outside of the United States. Kinex has raised over $190 Million since its inception and has acquired 344 stockholders as a result of its fund raising activities.

As the attached Table of Organization illustrates, the majority of Kinex's stockholders own a relatively small percentage of Kinex and, individually, have no meaningful control over Kinex. Both Kinex and the Applicant carefully reviewed the Application instructions and the NYS Department of Health's response to Question 3 of the Questions and Answers released on or about May 22, 2015 to determine which entities and persons in the Table of Organization were required by the Department of Health to submit affidavits with the Application. Applicant, like the party that submitted Question 3, had questions about the scope of parties from whom the Department of Health requires affidavits. As directed by the Department of Health in Question 3, Applicant has submitted affidavits from all "shareholders with a ten (10) percent or greater ownership in the company." Applicant has also included the Table of Organization so that the Department of Health has a complete picture of the direct and indirect ownership of the Applicant as well as an opportunity to make inquiry if needed.

If you have any questions or concerns, please do not hesitate to contact Mr. Steve Adams at (716) 898-8626.

Sincerely,

Flint D. Besecker
Kinex Pharmaceuticals, Inc.
Board Director & Chief Operating Officer

FIRST NIAGARA

May 14, 2015

Flint D. Besecker
Chief Operating Officer
Kinex Pharmaceuticals, Inc.
701 Ellicott Street
Buffalo, NY 14203

Dear Flint:

This letter confirms that Kinex Pharmaceuticals, Inc. has on deposit with FNFG and available for its immediate use in excess of $60 million in unrestricted cash or cash equivalents. We appreciate your ongoing business and look forward to continuing to serve your corporate banking needs in the future.

Sincerely,

Richard C. Hamister
First Vice President
Private Client Services

Kinex Supportive Pharmaceuticals LLC
Index for Application and Supplemental Material for the Registered Organization Application (DOH – 5138)

Application Tab	Application Section
	Cover letter of introduction to the application.
Tab 1	Checks for application fees placed in marked envelopes (2)
Tab 2	Completed NYSDOH Application for Registration as a Registered Organization (DOH-5138)
Tab 3	Index for Material Supplemental to Certain Sections of DOH-5138 and required Attachments.
Tab 4	Non-refundable application fee of $ 10,000. Conditionally refundable registration fee in amount of $200,000.
Tab 5	Legal Disclosure Forms related to Section H of the application.
Tab 6	Attachment A. Identification of real property, buildings, and facilities.
Tab 7	Attachment B. Identification of all equipment used for production and distribution of medical marijuana.
Tab 8	Attachment C. Copies of applicable executed and proposed deeds, leases, rental agreements, or executed contracts related to property use.
Tab 9	Attachment D. Operating Plan
Tab 10	Attachment E. Applicant's organization and operational documents.
Tab 11	Attachment F. Executed labor peace agreement.
Tab 12	Attachment G. Financial statement for business details and transactions connected with registered organization application.
Tab 13	Attachment H. Security Plan.
Tab 14	Attachment I. Financial statement for business details and transactions connected with registered organization application.
Tab 15	Attachment J. Staffing plan
Tab 16	Attachment K. Proof from local service provider that applicant's manufacturing and dispensing facilities are located with access to internet connectivity.
Tab 17	Attachment L. Timeline demonstrating estimated timeframe from growing marijuana to production of final approved product.

Tab 18	Attachment M. Attestation that applicant is able to comply with applicable state and local laws and regulations.
Appendix A.	Appendix A. Individual disclosure Affidavits.
Appendix B.	Appendix B. Architectural Program
Letters of Support	Letters of Support from local municipal officials and other elected officials representing locations of Kinex Supportive Pharmaceuticals, LLC registered organization operation.

Attachment A.
Identification Of Real Property for Cultivation, Manufacturing and Dispensaries

Background

As a Buffalo, NY located company, Kinex had several goals with evaluating real property for the cultivation and manufacturing center and location of the four dispensaries. To maintain effective support and supervision to the new subsidiary enterprise and also continue to enhance the identity of Kinex as a western New York company, it was preferable to locate the cultivation and manufacturing center in western New York.

An existing location with an existing serviceable building became a preference based on the contemplated period for implementation and meeting a good faith effort to demonstrate operational status for the registered organization by the statutory goal of January 2016. Further, understanding the New York perspective of cautiously introducing the availability of medical marijuana by beginning with limited eligible patient conditions, the cultivation and manufacturing center's attributes for beginning operations and at a later time expand capacity became a preference. Also, overall cost effectiveness to one of the largest capital costs of the project is another important factor.

Adhering to New York State requirements for distance away from schools, places of worship, and similar community resources is an obvious parameter. Moreover, the location planned for location of the cultivation – manufacturing center requires characteristics and resources typical of a manufacturing location and therefore most likely away from residential and community areas. In addition to the serviceable real property, the property parcel requires reliable sources of power, water, and sewer utilities, and also convenient access to highways for courier service to dispensary locations. As a result of the review, an existing building has been located in Lackawanna, NY.

Dispensaries pose other challenges due to the limit of four per registered organization. Kinex Supportive Pharmaceuticals completed a market estimate for all New York Counties employing county level and state level data to estimate clinically eligible populations by each New York County. The NYS Department of Health Regions organizes the data and analysis. The data display supports a finding that the Upstate urban counties of Erie, Monroe, Onondaga, and Albany were population hubs enhanced by in each case three to five contiguous counties that were generally within reasonable drive times to a central location, and represented access for 71 to 85 percent of the estimated clinically eligible patient population for the region. This along with major highway access to reach across each region began to form the criteria by which potential dispensary locations were identified and evaluated as meeting regulation parameters.

The Kinex Supportive Pharmaceutical intention is to serve all eligible patients that may seek medical marijuana across these Upstate regions from four centrally located dispensaries. The analysis result was that identified dispensary locations are located in Cheektowaga, NY for the Western region, Rochester for the Finger Lakes region, Syracuse for the Central region, and Latham, NY for the Capital region. Kinex Supportive will also pursue alternate delivery service arrangements for approval by NYSDOH after successfully receiving approval to become a registered organization in

order to effectively provide access for remotely located patients or others facing confining conditions that interfere with reaching a dispensary.

Description of Properties and Location to Carry Out Operations of Kinex Supportive Pharmaceuticals, LLC

Kinex Supportive Pharmaceuticals Cultivation and Manufacturing Center, 2303 Hamburg Turnpike, Lackawanna, NY.

The cultivation and manufacturing center was selected using the strictest interpretation of the medical marijuana regulations in addition to the Holder "letter" issued by the U.S. department of Justice. The proposed building is a portion of the former Bethlehem Steel Plant site in Lackawanna, NY, in Erie County NY. The facility is an existing structure with significant attributes leading to its selection. Highlights include:

- Security – The site has limited access points by road and excellent sight lines from the building and its perimeter.

- Distance away from restricted types of neighboring community institutions. The site is over 2,500 feet from any residence, schools, or places of worship.

- Speed to completion by January 2016. The existing structure provides for up to 32,000 square feet for the cultivation and manufacturing center. First phase development will make use of approximately 16,000 square feet of the structure that is able to be modified and completed to meet the law's objective for product availability by January, 2016. The building also has available space for expansion, particularly for additional cultivation space, adding to the cultivation and manufacturing center an additional approximately 16,000square feet.

- Brownfield qualified for re-use. Site mitigation has been completed. As an approved brownfield site and it is in the public's interest that the site obtains a sustainable form of reuse for economic benefit and to support employment.

- Industrial Utilities. The site has nearly unlimited utilities for electrical power, along with water and sewer availability to meet the cultivation and manufacturing requirements initially and upon expansion of the site based on demand for medical marijuana over time in the Upstate regions and elsewhere in New York.

- Design Strength. The Western NY winter weather and especially snow and ice loads upon structures are a challenge for greenhouse operations. This condition drove our important preference to select a steel building to alleviate the weather related risk interfering with cultivation and manufacturing operations.

- Business Plan Cost Effectiveness Benefit. Combined, these and other factors provide a cumulative, cost effective benefit to the entire enterprise as the cultivation and manufacturing center is a significant application of capital for Kinex Supportive Pharmaceuticals, LLC.

Dispensary Locations

All proposed dispensary locations have the following characteristics:

- All meet state regulatory requirements.
- All are located in commercially zoned locations.
- Architectural Programs are complete and can be found in Appendix B.
- Their locations provide for reasonably good access with travel routes and should provide good access to certified patients.
- The dispensary locations generally will be leased at reasonable costs.
- Upon introduction of an approved alternate product delivery strategy, the dispensary locations will also act as “hubs” for distribution and control to “hard to reach” certified patients within each region, and in coordination with the cultivation and manufacturing center. This will be elaborated as part of a separate protocol submitted when the Department of Health indicates that such information should be submitted.

The Kinex Supportive Dispensary locations are:

- 81 Benbro street, Cheektowaga, NY 14225
- 135 Corporate Woods, Rochester, NY 14623
- 2320 Court Street, Syracuse, NY 13206
- 933 New Loudon Road, Latham, NY 12110

The dispensary locations with additional information are identified in the Medical Marijuana Program Application (DOH-5138) in Tab 2, and also in Appendix B., Architectural Program.

The anticipated source and application of funds for purchase, lease, and construction activities is from Kinex Pharmaceuticals, LLC from lending instruments including mortgages, loans, and its assets. Projected date of construction is provided in the timeline found in Tab 17 as Attachment L.

Kinex Supportive Pharmaceuticals

ATTACHMENT M

To: New York State Department of Health

Bureau of Narcotic Enforcement

Medical Marijuana Program

150 Broadway

Albany, New York 12204

Re: Statement of Compliance with State and Local Laws and Regulations

Date: June 1, 2015

The Applicant has consulted with New York legal counsel concerning the activities in which Applicant intends to engage as a registered organization to manufacture and dispense approved medical marijuana products in New York. Based on such consultation, the Applicant has determined, as required by 10 NYCRR § 1004.5(b)(8), that it is able to comply with all such state and local laws and regulations applicable to a registered organization, including without limitation, New York Public Health Law, Section 3360 et seq., 10 NYCRR Part 1004, and local zoning laws.

By: _____

Chief Operating Officer

Kinex Supportive Pharmaceuticals, LLC

Kinex
Supportive
Pharmaceuticals

ATTACHMENT M

To: New York State Department of Health

Bureau of Narcotic Enforcement

Medical Marijuana Program

150 Broadway

Albany, New York 12204

Re: Statement of Compliance with State and Local Laws and Regulations

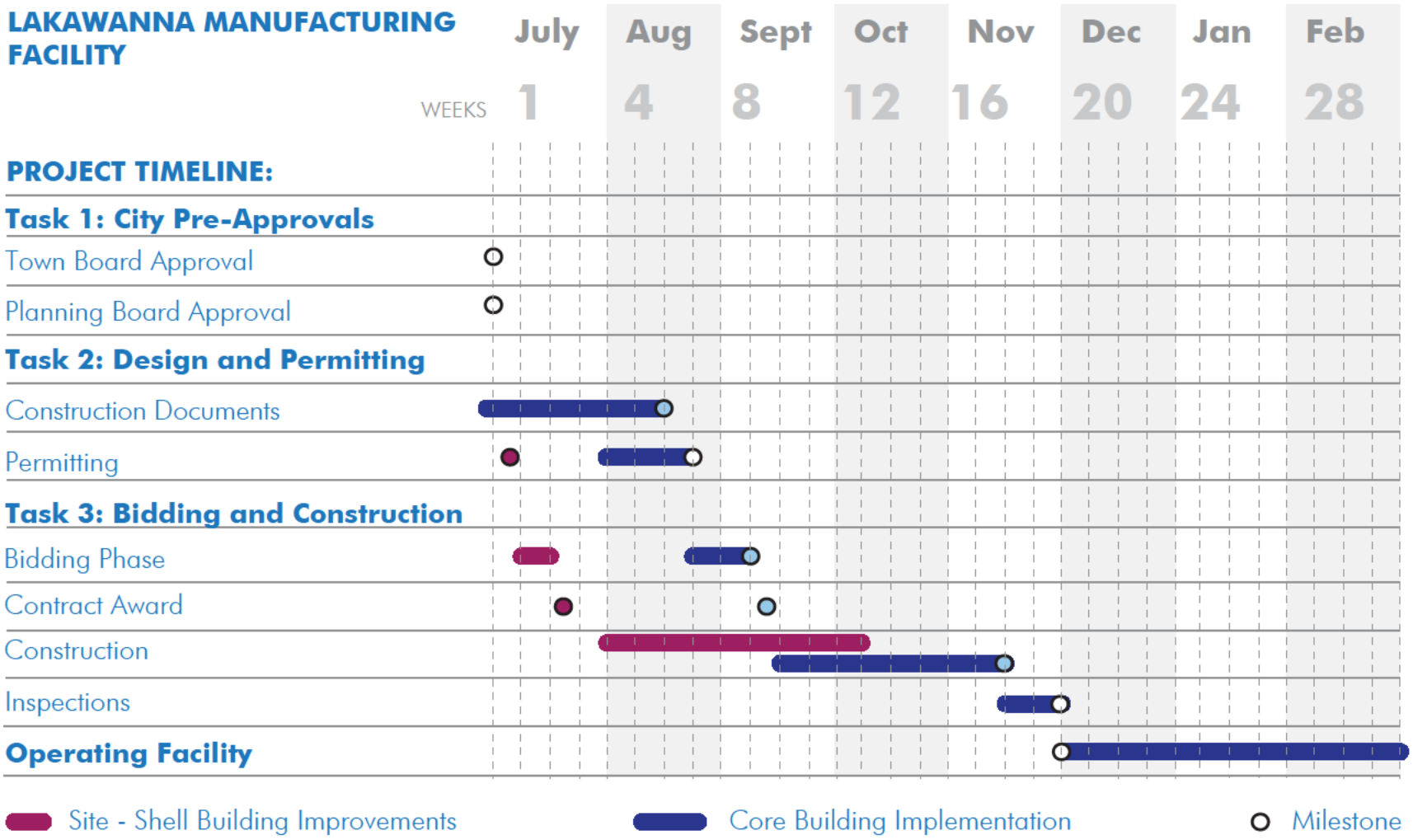
Date: June 2, 2015

The Applicant has consulted with New York legal counsel concerning the activities in which Applicant intends to engage as a registered organization to manufacture and dispense approved medical marijuana products in New York. Based on such consultation, the Applicant has determined, as required by 10 NYCRR § 1004.5(b)(8), that it is able to comply with all such state and local laws and regulations applicable to a registered organization, including without limitation, New York Public Health Law, Section 3360 et seq., 10 NYCRR Part 1004, and local zoning laws.

By: Stephen A. Panaro, Ph.D.

Chief Executive Officer

Kinex Supportive Pharmaceuticals, LLC


LAKAWANNA MANUFACTURING FACILITY
July
Aug
Sept
Oct
Nov
Dec
Jan
Feb
WEEKS
1
4
8
12
16
20
24
28
PROJECT TIMELINE:
Task 1: City Pre-Approvals
Town Board Approval
Planning Board Approval
Task 2: Design and Permitting
Construction Documents
Permitting
Task 3: Bidding and Construction
Bidding Phase
Contract Award
Construction
Inspections
Operating Facility
Site - Shell Building Improvements
Core Building Implementation
Milestone

Appendix B: Architectural Program

A SEPARATE "APPENDIX B" SHALL BE COMPLETED FOR EACH SEPARATE BUILDING AND/OR FACILITY INCLUDED IN THE ORGANIZATION'S BUSINESS PLAN

COMPANY INFORMATION	
Business Name:	Kinex Supportive Pharmaceuticals
Facility Type:	Manufacturing Facility ☑ Dispensing Facility ☐
Use and Occupancy Classification:	F-1 Moderate Hazard
Building Construction Type and Classification:	Type IIb
Facility Address:	Business Park lot 3-4, Highway #2, Lakawanna, NY 14218
Primary Contact Telephone number:	Jody Miller, MBA (716)440-0192
Primary Contact Fax number:	

PART I – ARCHITECTURAL PROGRAM & CONSTRUCTION TIMELINE:
Applicant shall identify planning requirements, including but not limited to:

☐	TOWN BOARD APPROVAL
☐	PLANNING BOARD APPROVAL
☐	ZONING BOARD OF APPEALS APPROVAL
☑	PREPARATION OF CONSTRUCTION DOCUMENTS
☑	BUILDING PERMIT
☑	BIDDING PHASE
☑	CONTRACT AWARD PHASE PER EACH APPLICABLE CONTRACTOR (Identify all that apply)
☑	COMMENCEMENT OF CONSTRUCTION
☑	COMPLETION OF CONSTRUCTION

Appendix B – Architectural Program

PART II – SITE PLAN(S)

Applicant shall provide the appropriate details for each of the following by identifying the location and dimension on the Site Plan attached to the application for each building location.

	☑ Entrance and Exits ☑ Public Parking Spaces ☑ Staff Parking Spaces ☑ Accessible Parking Spaces ☑ Accessible Route(s)	☑ Fire Lane and/or Fire Apparatus Road ☑ Percentage of Green Space ☑ Location of Emergency Power Systems ☑ Loading & Unloading ☑ Security Gates & Fences

PART III – ENERGY SOURCES & ENGINEERING SYSTEMS:

Applicant shall provide the following minimum information to outline the specifications relating to the energy sources and engineering systems of each building included in the application.

Energy Source:

☑ Natural Gas ☐ Oil ☑ Electric
☑ Solar ☐ Other _____

Engineering Systems:

☑ Heating System: Type gas boile, Size 2000mbh Efficiency 95%,
Ventilation Requirements per ashre standars

☑ Cooling System: Type chiller, Size 100 ton Efficiency 10.1 eer,
Ventilation Requirements per ashre standards

☑ Ventilation & Humidification Systems:
Type ultrsonic, Size tbd, Efficiency tbd,
Ventilation Requirements per ashre standards

☑ Electrical Distribution Available 480/277 volt

☑ Water Supply: Municipal Water Service X or Private Well Water _____

☑ Sewage: Municipal Sewer System X or Private Septic System _____

☑ Emergency Power System:
Type diesel, Size 500 kw Efficiency 75-80%,

Appendix B – Architectural Program

PART IV – BUILDING CODE COMPLIANCE: (pages 3-13)	
CHECK ALL APPLICABLE CODES FOR THE FACILITY	
☑	2010 BUILDING CODE OF NYS
☑	2010 FIRE CODE OF NYS
☑	2010 PLUMBING CODE OF NYS
☑	2010 MECHANICAL CODE OF NYS
☑	2010 FUEL GAS CODE OF NYS
☑	2010 PROPERTY MAINTENANCE CODE OF NYS
☑	2010 ENERGY CONSERVATION CONSTRUCTION CODE OF NYS
☑	2012 IECC COMMERCIAL PROVISIONS
☑	2010 EXISTING BUILDING CODE OF NYS
☑	NEC NATIONAL ELECTRIC CODE, (Specify Applicable Version)
☐	2014 NY CITY CONSTRUCTION CODE
☐	2008 NY CITY CONSTRUCTION CODE
☐	1968 NY CITY CONSTRUCTION CODE
☑	NFPA 101-06 LIFE SAFETY CODE
☑	ICC/ANSI A117.1-03 ACCESSIBLE AND USABLE BUILDINGS AND FACILITIES
☐	OTHER

Appendix B – Architectural Program

Select Project Type: Check all that apply. Refer to the Existing Building Code for definitions.	☐ New Building ☐ Repair ☐ Alteration Level 1 ☐ Alteration Level 2	☑ Alteration Level 3 ☐ Change of Occupancy ☐ Addition ☐ Historic Building	☐ Demolition ☐ Chapter 3. Prescriptive Compliance Method ☐ Chapter 13. Performance Compliance Method
Select Work Involved: Check all that apply.	☑ General Construction ☑ Roofing ☑ Asbestos Abatement/Environmental ☑ Fire Alarm	☑ Structural ☑ Mechanical ☑ Plumbing ☑ Electrical	☑ Site Work ☑ Sprinkler ☑ Elevators ☐ Other:_____

CODE COMPLIANCE REVIEW

Applicant shall provide all applicable information in regards to the code topic and section listed below.

1 Code Compliance Review is based on the 2010 NY State Building Code for New Construction. If any other building code applies to the location or type of construction, provide applicable code and sections that most closely relates and references the code topic and information in the code sections listed below. Provide appropriate abbreviations for other applicable codes, such as: **FC:** ***Fire Code*****, PC:** ***Plumbing Code*****, MC:** ***Mechanical Code*****, FGC:** ***Fuel Gas Code*****, ECCC:** ***Energy Conservation Code.***

2. Provide the Required standard for each applicable code section. (i.e.: area, quantity, classification type, materials, hourly separation, etc.). If section does not apply, indicate one of the following with explanation: **NA:** *Not Applicable*, **NR:** *Not Required*, **NP:** *Not Permitted*

3 Provide your facilities "Actual" value for each required standard as per applicable code section.

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
1	Use & Occupancy Classification	302.1 - 312		Use & occupancy of this facility. Identify all applicable materials, class and quantities regarding Table 307.1.	F-1 Moderate Hazard	F-1 Moderate Hazard

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
2	Combustible Storage	413		All combustible storage areas and rooms, as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
3	Hazardous Materials	414		All hazardous materials stored or used as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
4	Hazardous Materials Control Areas	414.2		Provide additional information indicating number, size, materials stored, and quantity of each material.	NA	
5	Building Area & Height	501-507		Provide the building area & height Provide all calculations and cite applicable code sections for increased Building Area & Heights allowed per building code(s).	see additional information for calculations 3 stories 46,500sqft allowed	2 stories 32,958sqft
6	Incidental Use Areas	508.2		Identify all Incidental Use Areas and required fire separation of occupancies on Building Plans.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
7	Mixed Occupancies	508.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
8	Nonseparated Uses	508.3.2		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
9	Separated Uses (Ratio < 1)	508.3.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
10	Construction Classification	602		Provide Construction Classification per each building included in Application.	Type IIb	Type IIb
11	Fire Resistance Rating Reqm't for Building Elements	Table 601		Provide Fire Resistance Rating per each building element as per Table 601. Identify rating & elements on Building Plans.	not required	none provided

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
12	Exterior Wall Fire-Resistance Rating	Table 602		Identify required fire resistance rating of exterior walls on Building Plan(s).	NA	
13	Exterior Fire Separation Distance	Table 602		Identify required fire separation distance of exterior walls between Buildings on Plan.	none required when greater than 30'	actual distance 75' or greater therefore none required
14	Fire Walls	705		Provide code information and identify all applicable required Fire Wall(s) and fire resistance requirement on Building Plans.	NA	
15	Fire Barriers	706		Provide code information and identify all applicable required Fire Barrier(s) and fire resistance requirement on Building Plans.	3 hr fire barriers required between fire areas	seperate fire areas not required
16	Shaft Enclosures	707		Provide code information and identify all applicable required Shaft Wall(s) and fire resistance requirement on Building Plans.	2 hr shaft enclosures required	see plans
17	Fire Partitions	708		Provide code information and identify all applicable required Fire Partition(s) and fire resistance requirement on Building Plans.	1 hr fire partitions required	see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
18	Horizontal Assemblies	711		Provide code information and identify all applicable required Horizontal Assemblies and fire resistance requirement on Building Plans.	Not Required	
19	Fire Protection: Sprinkler System	903		Indicate Type of Sprinkler System: ☑ NFPA 13 ☐ NFPA 13 R ☐ NFPA 13D Provide code information of all applicable requirements for Automatic Sprinkler Systems with code section cited.	required	provided
20	Alt. Fire Extinguishing System	904		Provide code information of all applicable requirements for Alternative Automatic Fire-Extinguishing Systems with code section(s) cited.	NA	
21	Standpipe System	905		Provide code information of all applicable requirements for Standpipe Systems with code section(s) cited.	NA	
22	Fire Alarm & Detection Systems	907		Provide code information of all applicable requirements for Fire Alarm System(s) with code section cited. Indicate Type of Fire Alarm System ☐ Addressable ☑ Hardwired (zoned)	required with occupant load over 100	provided

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
23	Emergency Alarm System	908		Provide code information of all applicable requirements for Emergency Alarm Systems with code section cited.	NA	
24	Fire Department Connections	912		Identify Fire Department connections in accordance with NFPA applicable standard.	required	to be provided
25	Exits	1001.1 &2		Identify on the Building Plans and documents, per each door, the following information: door width, door height, direction of swing, type of construction, hourly rating, and door closures.	required	provided, see plans
26	Occupant Load	1004 & Table 1004.1.1		Identify the use/name of each room, dimensions of each room, and Occupant Loads per each room on the Building Plans.	total occupant load is 326	see plans for occupant loads of individual spaces
27	Egress Width	1005		Provide egress widths & cite applicable code section(s) and requirement(s) on the Building Plans	stairways .2 per occupant, other components .15	stairways 32" other 49"
28	Accessible Means of Egress	1007.1		Provide accessible means of egress as per Section 1007 & cite applicable code section(s) and requirement(s) on the Building Plans.	required	provided, see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
29	Doors, Gates, and Turnstiles	1008		Means of egress doors shall meet the requirements of this section.	required	Provided, See plans
30	Interior Stairs	1009		Identify the following information for each stairway on the Building Plan(s): the width of stairways; the height, width, depth and number of risers and treads; dimensions of landings; stairway construction type; and handrail height.	required	See plans
31	Ramps	1010.1		Identify the following information of each ramp, on the Building Plan(s): width; total vertical rise; length of ramp; and handrail height.	NA	
32	Common Path of Travel	1014.3		Identify on the Building Plan(s): the length of the "Common Path of Travel" per each room as per applicable building code requirements.	not greater than 100'	See plans
33	Exit Doorway Arrangement	1015		Identify on the Building Plan(s): applicable building code requirements for all Exits and Exit Access Doorways per each room and required exits in all buildings.	maximum occupant load with one means of egress is 49 people per space	See plans
34	Corridor Fire Rating	1017.1		Identify, on the Building Plan(s): all corridors with required fire resistance and the applicable fire rating.	1 hr fire resistance rating required in corridors	1hr provided See plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
35	Corridor Width	1017.2		Identify on the Building Plan(s): the width of all corridors. Provide applicable code section(s) and requirement(s).	49" min required	72" provided
36	Dead End Corridor	1017.3		Corridors shall not exceed the maximum dead end corridor length as per applicable code.	shall not exceed 50'	none provided
37	Number of Exits and Continuity	1019		Identify on the Building Plan(s): required number of exits, continuity and arrangement as per the applicable code requirements.	2 exits required	3 exits provided, additional exits provided out of spaces
38	Vertical Exit Enclosures	1020		Identify on the Building Plan(s): all applicable code requirements for each Vertical Exit Enclosure.	1hr fire resistance required	1hr fire resistance provided
39	Exit Passageways	1021		Identify on the Building Plan(s): all applicable code requirements for each Exit Passageway.	required	Provided
40	Horizontal Exits	1022		Identify on the Building Plan(s): all applicable code requirements for each Horizontal Exit.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
41	Exterior Exit Ramps & Stairways	1023		Identify on the Building Plan(s): all applicable code requirements for each exterior exit ramps and stairways.	NA	no exterior stairs or ramps are provided in the project
42	Exit Discharge	1024		Identify on the Building Plan(s): all applicable code requirements for each Exit Discharge.	required	provided, see plans
43	Accessibility	1101.1 - 1110 & ICC/A117. 1(03)		Identify on the Building Plan(s): all applicable code requirements such that the design and construction of each building/facility provides accessibility to physically disabled persons.	required	provided, see plans for door and fixture clearances
44	Energy Conservation	2010 NYS ECCC & IECC 2012		Identify the R-Value and U-Value of each construction component and assembly of the building envelope as required in the applicable energy and building code(s).	roofs R13+R13 or R20 cont Walls R13+R5.6 cont	min. Roofs R20 cont provided min. Walls R13+6 provided
45	Emergency & Standby Power	2702.1		Identify emergency & Standby Power locations and specifications of the system to be provided.	Required	provided, see electrical narrative
46	Smoke Control Systems	2702.2.2		Identify the Standby power for smoke control systems in accordance with Section 909.11 of NYS Building Code.	NA	smoke control systems not required

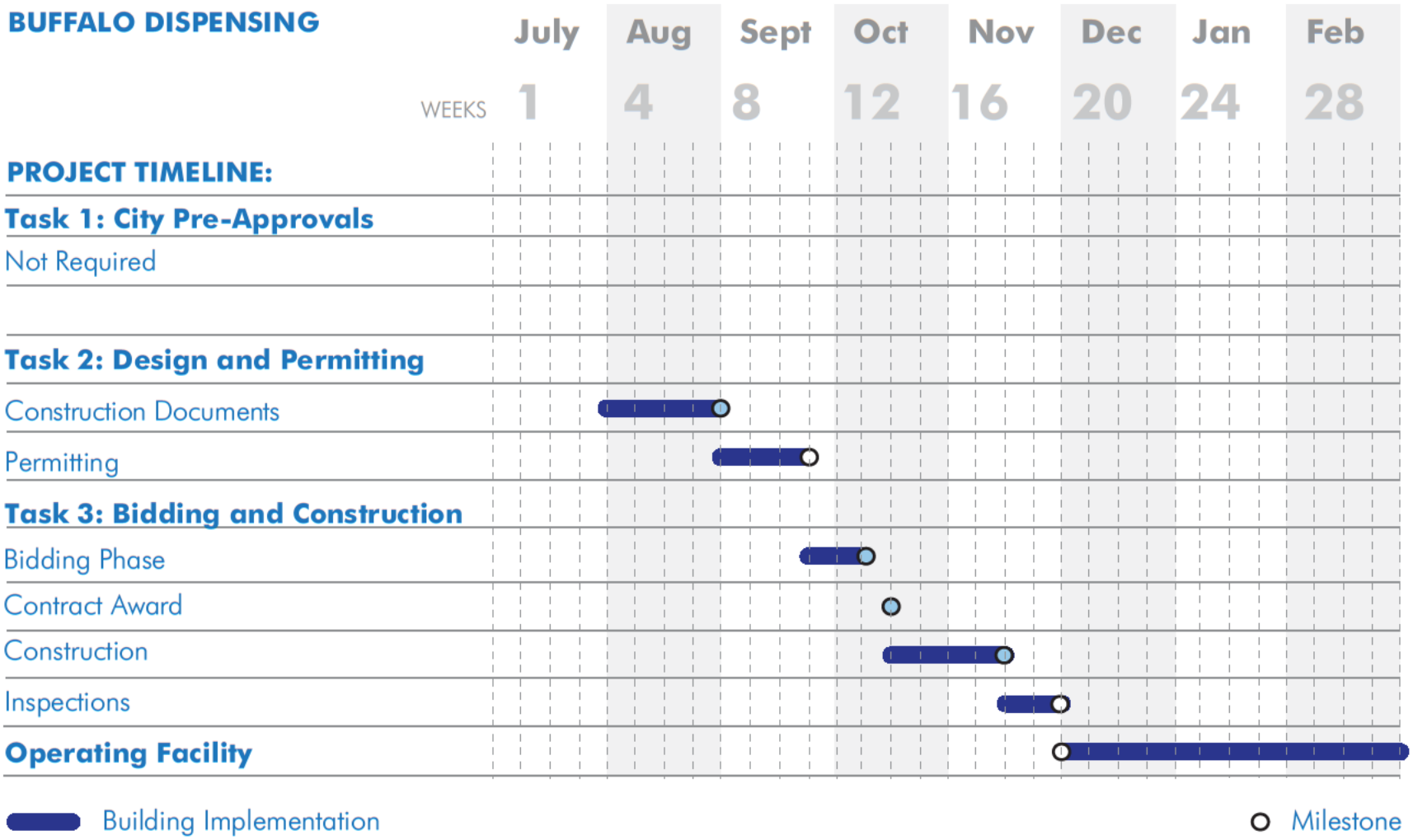
Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
47	Plumbing Fixture Count	2902.1		Identify on the Building Plan(s): the minimum plumbing facilities as per applicable plumbing code(s).	1 DF, 1 service sink, 4 WC M, 4WC F, 4Lav M, 4 Lav F	1 DF, 1 service sink, 4 WC M, 4WC F, 4Lav M, 4 Lav F
48	Available Street Water Pressure			Provide the available street or well water pressure.		80psi
49	Fire Apparatus Access Road	FC503.1		Identify on the Site Plan: Fire Apparatus Road, Fire Lane and other Fire Service requirements per applicable Building and Fire Codes.	see site plan	see site plan

APPENDIX "A"

MEP-1 - FLOOR PLAN

Redacted pursuant to N.Y. Public Officers Law, Art.6


BUFFALO DISPENSING
July
Aug
Sept
Oct
Nov
Dec
Jan
Feb
WEEKS
1
4
8
12
16
20
24
28
PROJECT TIMELINE:
Task 1: City Pre-Approvals
Not Required
Task 2: Design and Permitting
Construction Documents
Permitting
Task 3: Bidding and Construction
Bidding Phase
Contract Award
Construction
Inspections
Operating Facility
Building Implementation
Milestone

Appendix B: Architectural Program

A SEPARATE "APPENDIX B" SHALL BE COMPLETED FOR EACH SEPARATE BUILDING AND/OR FACILITY INCLUDED IN THE ORGANIZATION'S BUSINESS PLAN

COMPANY INFORMATION	
Business Name:	Kinex Supportive Pharmaceuticals
Facility Type:	Manufacturing Facility ☐ Dispensing Facility ☑
Use and Occupancy Classification:	Mechantile
Building Construction Type and Classification:	IIb
Facility Address:	81 Benbro Park, Suite 200, Cheektowaga, NY 14227
Primary Contact Telephone number:	Jody Miller, MBA (716)440-0192
Primary Contact Fax number:	

PART I – ARCHITECTURAL PROGRAM & CONSTRUCTION TIMELINE:
Applicant shall identify planning requirements, including but not limited to:

☐	TOWN BOARD APPROVAL
☐	PLANNING BOARD APPROVAL
☐	ZONING BOARD OF APPEALS APPROVAL
☑	PREPARATION OF CONSTRUCTION DOCUMENTS
☑	BUILDING PERMIT
☑	BIDDING PHASE
☑	CONTRACT AWARD PHASE PER EACH APPLICABLE CONTRACTOR (Identify all that apply)
☑	COMMENCEMENT OF CONSTRUCTION
☑	COMPLETION OF CONSTRUCTION

Appendix B – Architectural Program

PART II – SITE PLAN(S)

Applicant shall provide the appropriate details for each of the following by identifying the location and dimension on the Site Plan attached to the application for each building location.

	☑ Entrance and Exits ☑ Public Parking Spaces ☑ Staff Parking Spaces ☑ Accessible Parking Spaces ☑ Accessible Route(s)	☑ Fire Lane and/or Fire Apparatus Road ☑ Percentage of Green Space ☑ Location of Emergency Power Systems ☑ Loading & Unloading ☐ Security Gates & Fences

PART III – ENERGY SOURCES & ENGINEERING SYSTEMS:

Applicant shall provide the following minimum information to outline the specifications relating to the energy sources and engineering systems of each building included in the application.

Energy Source:

☑ Natural Gas ☐ Oil ☑ Electric
☐ Solar ☐ Other _____

Engineering Systems:

☑ Heating System: Type pkg RTU, Size _____ Efficiency _____,
Ventilation Requirements per ashre standars

☑ Cooling System: Type pkg RTU, Size _____ Efficiency _____,
Ventilation Requirements per ashre standards

☑ Ventilation & Humidification Systems:
Type pkg RTU, Size _____, Efficiency _____,
Ventilation Requirements per ashre standards

☑ Electrical Distribution Available 480/277 volt

☑ Water Supply: Municipal Water Service x or Private Well Water _____

☑ Sewage: Municipal Sewer System x or Private Septic System _____

☑ Emergency Power System:
Type batteries, Size varies Efficiency _____,

Appendix B – Architectural Program

PART IV – BUILDING CODE COMPLIANCE: (pages 3-13)	
CHECK ALL APPLICABLE CODES FOR THE FACILITY	
☑	2010 BUILDING CODE OF NYS
☑	2010 FIRE CODE OF NYS
☐	2010 PLUMBING CODE OF NYS
☐	2010 MECHANICAL CODE OF NYS
☐	2010 FUEL GAS CODE OF NYS
☑	2010 PROPERTY MAINTENANCE CODE OF NYS
☐	2010 ENERGY CONSERVATION CONSTRUCTION CODE OF NYS
☐	2012 IECC COMMERCIAL PROVISIONS
☑	2010 EXISTING BUILDING CODE OF NYS
☑	NEC NATIONAL ELECTRIC CODE, (Specify Applicable Version)
☐	2014 NY CITY CONSTRUCTION CODE
☐	2008 NY CITY CONSTRUCTION CODE
☐	1968 NY CITY CONSTRUCTION CODE
☑	NFPA 101-06 LIFE SAFETY CODE
☑	ICC/ANSI A117.1-03 ACCESSIBLE AND USABLE BUILDINGS AND FACILITIES
☐	OTHER

Appendix B – Architectural Program

Select Project Type: Check all that apply. Refer to the Existing Building Code for definitions.	☐ New Building ☐ Repair ☐ Alteration Level 1 ☑ Alteration Level 2	☐ Alteration Level 3 ☐ Change of Occupancy ☐ Addition ☐ Historic Building	☐ Demolition ☐ Chapter 3. Prescriptive Compliance Method ☐ Chapter 13. Performance Compliance Method
Select Work Involved: Check all that apply.	☑ General Construction ☐ Roofing ☐ Asbestos Abatement/Environmental ☐ Fire Alarm	☐ Structural ☐ Mechanical ☑ Plumbing ☑ Electrical	☑ Site Work ☐ Sprinkler ☐ Elevators ☐ Other:_____

CODE COMPLIANCE REVIEW

Applicant shall provide all applicable information in regards to the code topic and section listed below.

1. Code Compliance Review is based on the 2010 NY State Building Code for New Construction. If any other building code applies to the location or type of construction, provide applicable code and sections that most closely relates and references the code topic and information in the code sections listed below. Provide appropriate abbreviations for other applicable codes, such as: **FC:** ***Fire Code*****, PC:** ***Plumbing Code*****, MC:** ***Mechanical Code*****, FGC:** ***Fuel Gas Code*****, ECCC:** ***Energy Conservation Code.***
2. Provide the Required standard for each applicable code section. (i.e.: area, quantity, classification type, materials, hourly separation, etc.). If section does not apply, indicate one of the following with explanation: **NA:** *Not Applicable*, **NR:** *Not Required*, **NP:** *Not Permitted*
3. Provide your facilities "Actual" value for each required standard as per applicable code section.

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
1	Use & Occupancy Classification	302.1 - 312		Use & occupancy of this facility. Identify all applicable materials, class and quantities regarding Table 307.1.	M Mercantile	M Mercantile

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
2	Combustible Storage	413		All combustible storage areas and rooms, as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
3	Hazardous Materials	414		All hazardous materials stored or used as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
4	Hazardous Materials Control Areas	414.2		Provide additional information indicating number, size, materials stored, and quantity of each material.	NA	
5	Building Area & Height	501-507		Provide the building area & height Provide all calculations and cite applicable code sections for increased Building Area & Heights allowed per building code(s).	existing building, section does not apply	
6	Incidental Use Areas	508.2		Identify all Incidental Use Areas and required fire separation of occupancies on Building Plans.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
7	Mixed Occupancies	508.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
8	Nonseparated Uses	508.3.2		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
9	Separated Uses (Ratio < 1)	508.3.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
10	Construction Classification	602		Provide Construction Classification per each building included in Application.	Type IIb	Type IIb
11	Fire Resistance Rating Reqm't for Building Elements	Table 601		Provide Fire Resistance Rating per each building element as per Table 601. Identify rating & elements on Building Plans.	not required	none provided

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
12	Exterior Wall Fire-Resistance Rating	Table 602		Identify required fire resistance rating of exterior walls on Building Plan(s).	NA	
13	Exterior Fire Separation Distance	Table 602		Identify required fire separation distance of exterior walls between Buildings on Plan.	existing building, section does not apply	
14	Fire Walls	705		Provide code information and identify all applicable required Fire Wall(s) and fire resistance requirement on Building Plans.	NA	
15	Fire Barriers	706		Provide code information and identify all applicable required Fire Barrier(s) and fire resistance requirement on Building Plans.	2 hr fire barriers required between fire areas	provided in tenant seperations
16	Shaft Enclosures	707		Provide code information and identify all applicable required Shaft Wall(s) and fire resistance requirement on Building Plans.	2 hr shaft enclosures required	see plans
17	Fire Partitions	708		Provide code information and identify all applicable required Fire Partition(s) and fire resistance requirement on Building Plans.	1 hr fire partitions required	see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
18	Horizontal Assemblies	711		Provide code information and identify all applicable required Horizontal Assemblies and fire resistance requirement on Building Plans.	Not Required	
19	Fire Protection: Sprinkler System	903		Indicate Type of Sprinkler System: ☑ NFPA 13 ☐ NFPA 13 R ☐ NFPA 13D Provide code information of all applicable requirements for Automatic Sprinkler Systems with code section cited.	Not required under 12,000sqft	fire area under 12,000sqft
20	Alt. Fire Extinguishing System	904		Provide code information of all applicable requirements for Alternative Automatic Fire-Extinguishing Systems with code section(s) cited.	NA	
21	Standpipe System	905		Provide code information of all applicable requirements for Standpipe Systems with code section(s) cited.	NA	
22	Fire Alarm & Detection Systems	907		Provide code information of all applicable requirements for Fire Alarm System(s) with code section cited. Indicate Type of Fire Alarm System ☐ Addressable ☑ Hardwired (zoned)	required with occupant load over 500	occupant load is less than 500 therefore its not required

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
23	Emergency Alarm System	908		Provide code information of all applicable requirements for Emergency Alarm Systems with code section cited.	NA	
24	Fire Department Connections	912		Identify Fire Department connections in accordance with NFPA applicable standard.	NA	
25	Exits	1001.1 &2		Identify on the Building Plans and documents, per each door, the following information: door width, door height, direction of swing, type of construction, hourly rating, and door closures.	required	provided, see plans
26	Occupant Load	1004 & Table 1004.1.1		Identify the use/name of each room, dimensions of each room, and Occupant Loads per each room on the Building Plans.	total occupant load is 24	see plans for occupant loads of individual spaces
27	Egress Width	1005		Provide egress widths & cite applicable code section(s) and requirement(s) on the Building Plans	stairways .3 per occupant, other components .2	stairways 8" other 5"
28	Accessible Means of Egress	1007.1		Provide accessible means of egress as per Section 1007 & cite applicable code section(s) and requirement(s) on the Building Plans.	required	provided, see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
29	Doors, Gates, and Turnstiles	1008		Means of egress doors shall meet the requirements of this section.	required	Provided, See plans
30	Interior Stairs	1009		Identify the following information for each stairway on the Building Plan(s): the width of stairways; the height, width, depth and number of risers and treads; dimensions of landings; stairway construction type; and handrail height.	required	See plans
31	Ramps	1010.1		Identify the following information of each ramp, on the Building Plan(s): width; total vertical rise; length of ramp; and handrail height.	NA	
32	Common Path of Travel	1014.3		Identify on the Building Plan(s): the length of the "Common Path of Travel" per each room as per applicable building code requirements.	not greater than 75'	See plans
33	Exit Doorway Arrangement	1015		Identify on the Building Plan(s): applicable building code requirements for all Exits and Exit Access Doorways per each room and required exits in all buildings.	maximum occupant load with one means of egress is 49 people per space	See plans
34	Corridor Fire Rating	1017.1		Identify, on the Building Plan(s): all corridors with required fire resistance and the applicable fire rating.	1 hr fire resistance rating required in corridors	1hr provided See plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
35	Corridor Width	1017.2		Identify on the Building Plan(s): the width of all corridors. Provide applicable code section(s) and requirement(s).	NA	none provided
36	Dead End Corridor	1017.3		Corridors shall not exceed the maximum dead end corridor length as per applicable code.	shall not exceed 20'	none provided
37	Number of Exits and Continuity	1019		Identify on the Building Plan(s): required number of exits, continuity and arrangement as per the applicable code requirements.	1 exits required	1 exit provided
38	Vertical Exit Enclosures	1020		Identify on the Building Plan(s): all applicable code requirements for each Vertical Exit Enclosure.	NA	no vertical exit enclosures
39	Exit Passageways	1021		Identify on the Building Plan(s): all applicable code requirements for each Exit Passageway.	required	Provided
40	Horizontal Exits	1022		Identify on the Building Plan(s): all applicable code requirements for each Horizontal Exit.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
41	Exterior Exit Ramps & Stairways	1023		Identify on the Building Plan(s): all applicable code requirements for each exterior exit ramps and stairways.	NA	no exterior stairs or ramps are provided in the project
42	Exit Discharge	1024		Identify on the Building Plan(s): all applicable code requirements for each Exit Discharge.	required	provided, see plans
43	Accessibility	1101.1 - 1110 & ICC/A117. 1(03)		Identify on the Building Plan(s): all applicable code requirements such that the design and construction of each building/facility provides accessibility to physically disabled persons.	required	provided, see plans for door and fixture clearances
44	Energy Conservation	2010 NYS ECCC & IECC 2012		Identify the R-Value and U-Value of each construction component and assembly of the building envelope as required in the applicable energy and building code(s).	existing building, section does not apply	
45	Emergency & Standby Power	2702.1		Identify emergency & Standby Power locations and specifications of the system to be provided.	NA	
46	Smoke Control Systems	2702.2.2		Identify the Standby power for smoke control systems in accordance with Section 909.11 of NYS Building Code.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
47	Plumbing Fixture Count	2902.1		Identify on the Building Plan(s): the minimum plumbing facilities as per applicable plumbing code(s).	1 DF, 1 service sink, 1 WC M, 1WC F, 1Lav M, 1Lav F	1 DF, 1 service sink, 1 WC M, 1WC F, 1Lav M, 1 Lav F
48	Available Street Water Pressure			Provide the available street or well water pressure.	existing building, TBD	
49	Fire Apparatus Access Road	FC503.1		Identify on the Site Plan: Fire Apparatus Road, Fire Lane and other Fire Service requirements per applicable Building and Fire Codes.	see site plan	see site plan

THIS DOCUMENT CONTAINS SEVERAL SECURITY FEATURES ON A BLUE BACKGROUND. HOLD DOCUMENT UP TO LIGHT TO VIEW TRUE WATERMARK.

FIRST NIAGARA

PAYABLE AT
First Niagara Bank
LOCKPORT, NY 14094

TELLER CHECK

[redacted]

50-7044/2223

REMITTER KINEX SUPPORTIVE PHARMA

06/01/2015

$10,000.00

PAY ***TEN THOUSAND and 00/100***USDollars

TO THE ORDER OF NEW YORK STATE DEPARTMENT OF HEALTH

Security features included. Details on back.

BRANCH NUMBER: 046

AUTHORIZED SIGNATURE

MP

8040

[redacted]

THIS DOCUMENT CONTAINS SEVERAL SECURITY FEATURES ON A BLUE BACKGROUND. HOLD DOCUMENT UP TO LIGHT TO VIEW TRUE WATERMARK.

FIRST NIAGARA

PAYABLE AT
First Niagara Bank
LOCKPORT, NY 14094

TELLER CHECK

[redacted]

50-7044/2223

REMITTER KINEX SUPPORTIVE PHARMA

06/01/2015

$200,000.00

PAY ***TWO HUNDRED THOUSAND and 00/100***USDollars

TO THE ORDER OF NEW YORK STATE DEPARTMENT OF HEALTH

Security features included. Details on back.

BRANCH NUMBER: 046

AUTHORIZED SIGNATURE

[redacted]

Kinex
Pharmaceuticals

Howard A. Zucker, M.D., J.D.
Commissioner of Health
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

June 2, 2015

Dear Dr. Zucker,

Kinex Pharmaceuticals, Inc., (Kinex) on behalf of our wholly owned subsidiary, Kinex Supportive Pharmaceuticals, LLC is pleased to submit this license application in support of the Compassionate Care Act. Kinex is a global oncology pharmaceutical company with its principal offices located in Buffalo New York. We currently employ approximately 240 professionals dedicated to drug development and formulation, pharmaceutical manufacturing, and research. Our personnel have backgrounds and advanced degrees in pharmacology, regulatory compliance, medical degrees, quality control, chemistry, biology and pharmacovigilance. Our existing business model includes the harvesting of the biomass from the Yew tree to chemically synthesize into paclitaxel which is a widely used anti-cancer pharmaceutical product. We believe synthesizing the active pharmaceutical ingredient from the marijuana plant into a safe, effective and compliant medical delivery mechanism for patients is a logical extension of our existing skill sets, capabilities and business.

Through our wholly owned subsidiary QuaDPharma, we have an existing FDA regulated pharmaceutical manufacturing site in Erie County, NY and an existing pharmacy license currently regulated through New York. Having recently raised $75 million in equity from investors, we also possess substantial cash liquidity to execute our business plan in New York if granted a license.

Importantly, from a patient perspective, we are strong believers in the medical applicability and symptom management benefits of marijuana as a mechanism to ease the symptom burdens of patients suffering from advanced disease. Certain of our executives have previous cutting edge palliative care experience in New York State having implemented palliative care medical service models in all settings including the home, hospital systems, long-term care and physician office. Our applicant's Medical Director, Dr. Christopher Kerr, currently oversees a Palliative Care physician practice that manages and treats the symptoms of over 9,000 patients annually in Western New York.

We believe our application is complete and were prepared to the best of our ability and understanding of the guidelines recently promulgated by NYS DOH. We look forward to your feedback and will make ourselves available to answer any specific or clarifying questions you may have during your review.

Sincerely,

Flint D. Besecker
Kinex Pharmaceuticals, Inc.
Chief Operating Officer & Board Director

Stephen Panaro, PhD
Kinex Supportive Pharmaceutics, LLC (Applicant)
Chief Executive Officer

ATTACHEMENT D

KINEX SUPPORTIVE PHARMACEUTICALS

Operational & Management Plan

Table of Contents

[redacted]

[redacted]

[redacted]

[redacted]

Section 1: Manufacturing

1.1 Site Selection

Our manufacturing site has been selected utilizing the strictest interpretation of the New York State standards and further the "Holder Letter" issued by the Department of Justice. The building as proposed sits on the Former Bethlehem Steel Plant site, in the city of Lackawanna, County of Erie, NY. The facility is an existing structure with significant attributes leading to our decision to utilize this site.

Highlights Include:

- **Security** – This site has limited access points via road and excellent site lines.
- **Distance** – This site is over 2000 ft. from any residence, including schools or places of worship
- **Brownfield Qualified** - This site is an approved Brownfield site and it is in the public's interest that the site be re-utilized. (mitigation has been completed)
- **Industrial Utilities** – This site has nearly unlimited utilities at the site and has support from utilities to supply our needs
- **Speed to Market** – The existing structure is capable of being modified to meet the January objective of product availability
- **Design Strength** – The Western NY snow loads are a challenge for greenhouse operators thus driving us to select a steel building that completely removes this risk

1.1.1 Design and Construction

(a) The facility used in the manufacture, packaging, labeling, or holding of marijuana-derived products will be suitable in size, construction, and design to facilitate maintenance, cleaning and/or sanitizing, as applicable to the operation.

(b) The facility will have adequate space for the orderly placement of equipment and materials to prevent mix-ups of components, packaging components, in-process materials, marijuana, or marijuana-derived products during manufacturing, packaging, labeling, or holding.

(c) The facility will be designed to reduce the potential for contamination of components, packaging components, marijuana, marijuana-derived products, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. The design and construction will include:

(1) Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair;

(2) Fixtures, ducts, and pipes that do not contaminate components, packaging components, in-process materials, marijuana or marijuana-derived products, or contact surfaces by dripping or other leakage, or condensate;

(3) Aisles or working spaces between equipment and walls that are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, packaging components, in-process materials, marijuana or marijuana-derived products, or contact surfaces with clothing or personal contact.

(4) Safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials will be used when the light bulbs, fixtures, skylights or other glass or glass-like materials are suspended over exposed components, packaging components, in-process materials, or marijuana or marijuana-derived products, unless the facility is otherwise constructed in a manner that will protect against contamination of components, packaging components, in-process materials, or marijuana or marijuana-derived products in case of breakage of glass or glass-like materials.

(d) The facility will have separate or defined areas, or other control systems such as computerized inventory controls or automated systems of separation, to prevent cross-contamination and mix-ups of components, marijuana, or marijuana-derived products during any of following operations that take place in the facility:

(1) Receipt, identification, storage, and withholding from use of quarantined components, packaging components, in-process materials, marijuana, or marijuana-derived products pending disposition by the Quality Control Officer;

(2) Storage of approved components, packaging components, marijuana, or marijuana-derived products.

(3) Storage of rejected components, packaging components, in-process materials, marijuana, marijuana-derived products, and marijuana waste pending return to their supplier or destruction;

(4) Storage of in-process materials pending normal further processing;

(5) Storage of components, packaging components, in-process materials, and products pending reprocessing;

(6) Manufacturing operations;

(7) Packaging and labeling operations;

(8) Separation of the manufacturing, packaging, labeling, and holding of different product types including different types of marijuana or marijuana-derived products and other products handled in the same facility;

(9) Performance of laboratory analyses and storage of laboratory supplies and

samples, as applicable;

(10) Cleaning and sanitation of contact surfaces.

(e) Water will be provided that is:

(1) Safe and sanitary, at suitable temperatures, and under pressure as needed, for all uses where water does not become a component of the marijuana-derived product; and

(2) Compliant with applicable state and local potable water requirements and with other requirements as necessary to ensure the water does not contaminate the marijuana-derived product, for all uses where such water may become a component of the marijuana-derived product, e.g., when such water contacts components, packaging components, in-process materials, marijuana or marijuana-derived products, or any contact surface.

(f) Heating, ventilating, cooling, and air filtration will be installed and maintained in the facility as needed to ensure the quality of the product.

(1) Ventilation equipment such as filters, fans, exhausts, dust collection, and other air-blowing equipment will be provided in areas where odors, dust, and vapors (including steam and noxious fumes) may contaminate components, packaging components, in-process materials, marijuana or marijuana-derived products, or contact surfaces.

(2) When fans, compressed air, or other air-blowing equipment are used, such equipment will be designed, located, and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, packaging components, in-process materials, marijuana, marijuana-derived products, or contact surfaces.

(3) Equipment that controls temperature, humidity, and/or microorganisms will be provided, when such equipment is necessary to ensure the quality of the product.

(g) The plumbing in the facility will be of an adequate size and design and be adequately installed and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the facility;

(2) Properly convey sewage and liquid disposable waste from the facility;

(3) Avoid being a source of contamination to components, packaging components, in-process materials, marijuana derived products, water supplies, or any contact surface, or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Not allow backflow from, or cross connection between, piping systems

that discharge waste water or sewage and piping systems that carry water used for manufacturing marijuana-derived products, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.

(h) Personnel will be provided with adequate, readily accessible toilet facilities that are:

(1) Maintained in a clean and sanitary condition;

(2) Adequately stocked with toilet paper, soap, and single use paper towels or other drying devices;

(3) Kept in good repair at all times

(4) Equipped with signage advising personnel of the necessity of washing hands prior to returning to work;

(5) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.

(i) Airborne contamination from toilet facilities will be prevented from contacting components, packaging components, in-process materials, marijuana- derived products, or contact surfaces, for example by providing adequate physical separation of toilet facilities from manufacturing, packaging, labeling, and holding operations, or by use of negative air pressure within the toilet facility.

(j) Adequate and convenient hand-washing facilities will be provided that are:

(1) Provided with running water of suitable temperature;

(2) Provided with effective hand cleaning and/or sanitizing preparations and single use paper towels or other drying devices;

(3) Located at points in the facility where good sanitary practices require personnel to wash their hands;

(4) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.

(k) Adequate lighting will be provided in:

(1) All areas where components, packaging components, in-process materials, marijuana, or marijuana-derived products are examined, manufactured, packaged, labeled, or held;

(2) All areas where contact surfaces are cleaned; and

(3) Hand-washing areas, dressing and locker rooms, and toilet facilities.

1.1.2 Fire prevention

(a) Any room in an indoor cultivation operation in which operational lighting, ballasts, or electrical control panels are located will be constructed with a

minimum of a one-hour firewall assembly.

(b)) Indoor cultivation operations will:
   (1) Provide at least one operating fire extinguisher, and
   (2) Provide additional fire extinguishers in a number proportional to the watts of supplemental lighting used in the facility (one fire extinguisher per every 10,000 watts of lighting), or in accordance with local fire code.

(c) Fire extinguishers will be:
   (1) Easily accessible to employees from every room and in each hallway of the facility;
   (2)) Maintained annually or as otherwise specified by the manufacturer; and
   (3) Of the appropriate class rating for the type of fire associated with the functions being performed in the facility (i.e., electrical, chemical).

(d) Flammable products will be stored in a properly marked fire containment cabinet or area.

(e) Signage that complies with National Fire Protection Association (NFPA) standard 704 will be placed at entrances to exposure areas.

1.1.3 Electrical system

(a) The cultivation operation's electrical system will be of sufficient capacity to handle the actual electrical load and be installed in accordance with an approved electrical permit.

(b) All electrical work and upgrades at cultivation operations will be performed with proper permitting.

(c) All electrical equipment used by a marijuana cultivation operation will be connected to the electrical system in accordance with the equipment manufacturer's recommendations.

This section focuses on the design and good manufacturing practices (GMP) requirements for HVAC systems in accordance with World Health Organization WHO guideline

1.1.4 Ventilation System

a) Areas for the manufacture of pharmaceuticals, where marijuana products starting materials and products, utensils, primary packing materials and equipment are exposed to the environment, will be defined as "controlled clean areas."

b) The achievement of a particular clean area condition depends on a number of criteria that will be addressed at the design and qualification stages. A suitable balance between the different criteria will be required in order to create an efficient clean area.

c) Some of the basic criteria to be considered which affects room cleanliness will include:

1. building finishes and structure
2. air filtration
3. air change rate or flushing rate
4. room pressure
5. location of air terminals and directional airflow
6. temperature
7. relative humidity
8. material flow
9. personnel flow
10. gowning procedures
11. equipment movement
12. process being carried out (open or closed system)
13. outside air conditions
14. occupancy
15. type of product
16. cleaning standard operating procedures (SOPs).

d) Air filtration and air change rates will be set to ensure that the defined clean area condition is attained.

e) Primarily the air change rate will be set to a level that will achieve the required clean area condition.

f) Air change rates will be conducted at a rate 4-10 air changes per hour depending on the clean room area.

g) Area condition required: whether a specific room cleanliness condition is in fact required and whether the room condition is rated for an "as-built," "at rest" condition, and "operational" condition, air change rate will be selected on need rather than tradition as shown in **Exhibit U.**

1. the product characteristics (e.g. odors, hygroscopicity, etc)
2. the quality and filtration of the supply air
3. particulates generated by the manufacturing process
4. particulates generated by the operators
5. configuration of the room and air supply and extract locations
6. sufficient air to achieve containment effect and to clean up the area
7. sufficient air to cope with the room heat load
8. sufficient air to balance extract rates
9. sufficient air to maintain the required room pressure.

h) Classification tests in the "as-built" condition will be carried out on the bare room, in the absence of any equipment or personnel.

i) Classification tests in the "at-rest" condition will be carried out with the equipment operating where relevant, but without any operators. Because of the amounts of dust

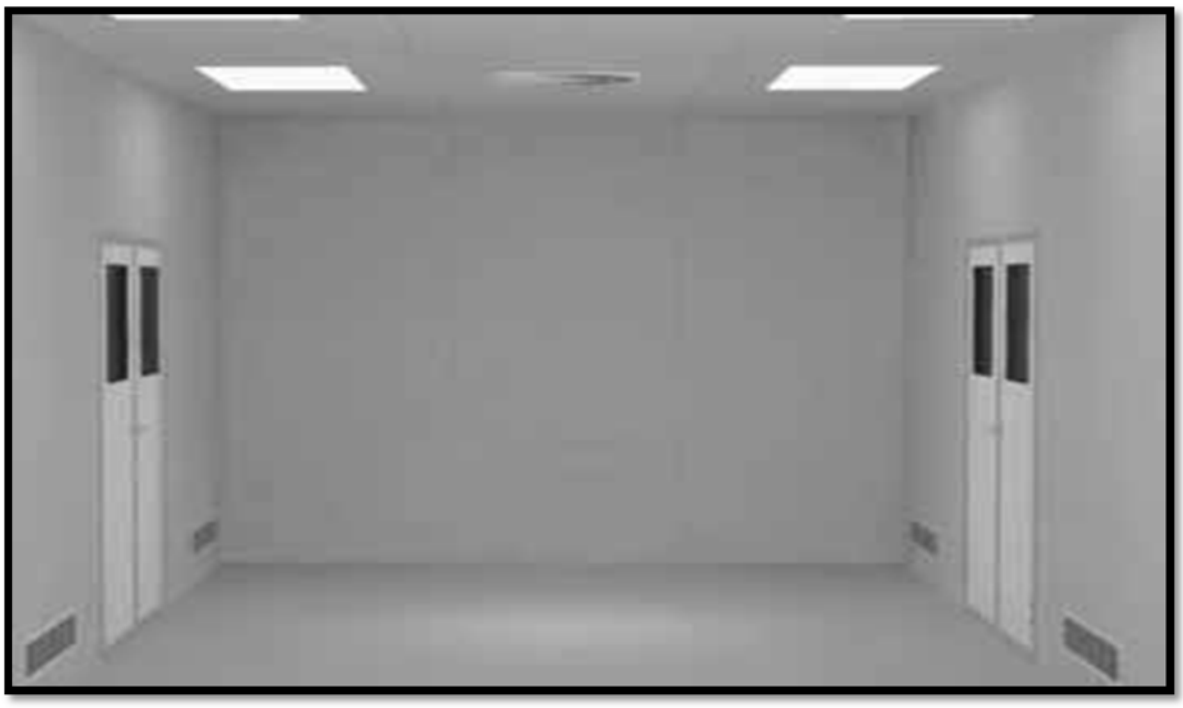
usually generated in a solid dosage facility, the clean area classifications would be rated for the "at-rest" condition.

j) Classification tests in the "operational" condition are normally carried out during the normal production process with equipment operating, and the normal number of personnel present in the room. Generally a room that is tested for an "operational" condition will be able to be cleaned up to the "at-rest" clean area classification after a short clean-up time. The clean-up time will be determined through validation and is generally of the order of 20 minutes.

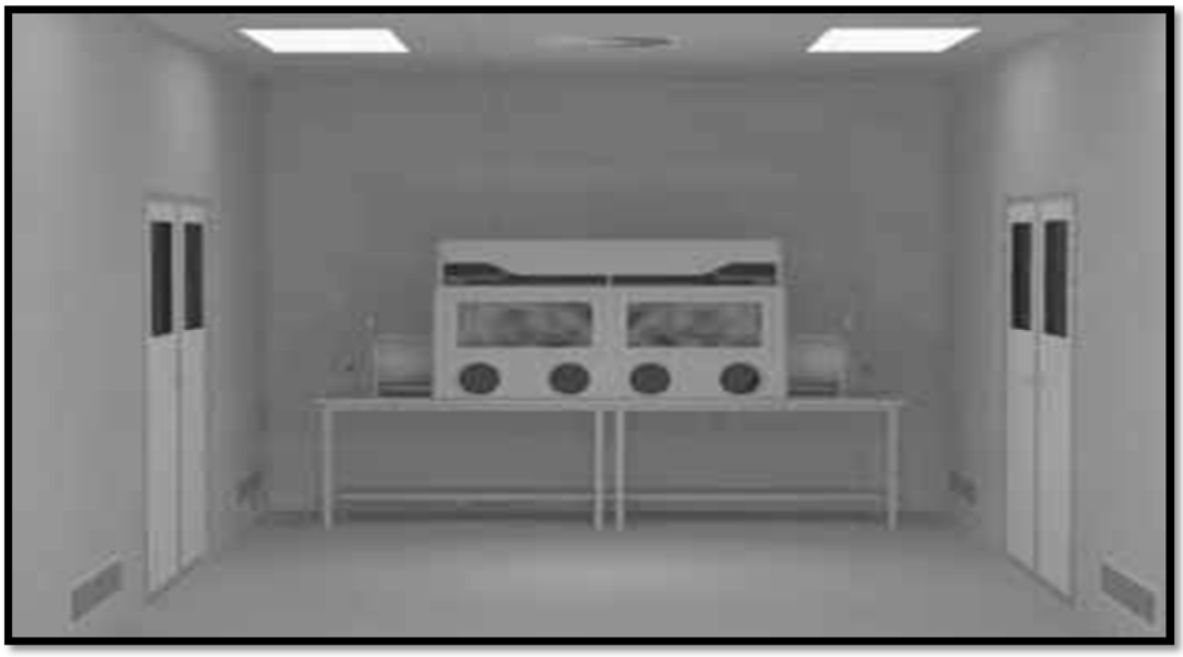
k) Products will be protected from contamination and cross-contamination during all stages of manufacture.

Exhibit U: "As-Built", "At-Rest", & "Operational" Condition

"As-built" condition



"At-rest" condition



“Operational” condition”

a) Airborne contaminants will be controlled through effective ventilation and filtration.

l) External contaminants will be removed by effective filtration of the supply air

m) Internal contaminants will be controlled by dilution and flushing of contaminants in the room, or by displacement airflow **(Exhibit V).**

n) Airborne particulates and the degree of filtration will be considered critical parameters with reference to the level of product protection required.

o) Personnel will not be a source of contamination.

p) The level of protection and air cleanliness for different areas will be determined according to the product being manufactured, the process being used and the product's susceptibility to degradation **(Exhibit W).**

Exhibit V: Methods to Flush Airborne Contaminants

Turbulent dilution of dirty air

Unidirectional displacement of dirty air

Exhibit W: Examples of Levels of Protection

Level	Condition	Example of area
Level 1	General	Area with normal housekeeping and maintenance where there is no potential for product contamination, e.g. warehousing.
Level 2	Protected	Area in which steps are taken to protect the pharmaceutical starting material or product from direct or indirect contamination or degradation, e.g. secondary packing, warehousing, first stage changerooms.
Level 3	Controlled	Area in which specific environmental conditions are defined, controlled and monitored to prevent contamination or degradation of the pharmaceutical starting material or product, e.g. where product, starting materials and components are exposed to the room environment; plus equipment wash and storage areas for equipment product contact parts.

a) The type of filters required for different applications depends on the quality of the ambient air and the return air (where applicable) and also on the air change rates. **Exhibit X** provides the recommended filtration levels for different levels of protection in a pharmaceutical facility.

b) Filter classes will always be linked to the standard test method because referring to actual filter efficiencies can be very misleading (as different test methods each result in a different value for the same filter). (Referring to filter classifications such as an 85% filter or a 5 μm filter are not valid classifications and will not be used, as this can lead to the incorrect filter being installed. Only the EN 779 and EN 1822 classifications, as per the table below, will be used **Exhibit Y.**

Exhibit X: Levels of Protection and Recommended Filtration

Level of protection	**Recommended filtration**
Level 1	Primary filters only (e.g. EN 779 G4 filters)
Level 2	Protected areas operating on 100% outside air: primary plus secondary filters (e.g. EN 779 G4 plus F8 or F9 filters)
Level 3	Production facility operating on recirculated plus ambient air, where potential for cross-contamination exists: Primaryplus secondary plus tertiary filters (e.g. EN 779 G4 plus F8 plus EN 1822 H13 filters) (for full fresh air system, without recirculation, G4 and F8 or F9 filters are acceptable)

a) Materials for components of an HVAC system will be selected with care so that they do not become a source of contamination. Any component with the potential for liberating particulate or microbial contamination into the air stream will be located upstream of the finalfilters.

Exhibit Y: Comparison of Filter Test Standards

Eurovent 4/5 Rating	ASHRAE 52.2	Eurovent 4/5 ASHRAE 52.1 BS6540 Part 1	Eurovent 4/5 ASHRAE 52.1 BS6540 Part 1	EN 779 & EN 1822		
(superseded)	Merv Rating	Average Arrestance A_m (%)	Average Dust Spot Efficiency E_m (%)	MPPS Integral Overall Efficiency (%)	EN Rating	
				99.999995	U17	EN 1822: 2009
				99.99995	U16	
EU 14				99.9995	U15	
EU 13	Merv 18			99.995	H14	
EU 12	Merv 17			99.95	H13	
EU 11				99.5	E12	
EU 10				95	E11	
EU 9	Merv 16		>95	85	E10	
EU 9	Merv 15		95		F9	EN779: 2002
EU 8	Merv 14		90		F8	
	Merv 13	>98	85	MPPS = Most Penetrating Particle Size	F7	
EU 7		>98	80			
	Merv 12	>95	75			
EU 6		>95	70		F6	
	Merv 11	>95	65			
		>95	60			
	Merv 10	>95	55			
EU 5	Merv 9	>95	50		F5	
	Merv 8	>95	45			
		>95	40			
	Merv 7	>90	35			
EU 4		>90	30		G4	
	Merv 6	90	25			
EU 3	Merv 5	85	20		G3	
		80	<20			
	Merv 4	75				
EU 2	Merv 3	70			G2	
	Merv 2	65				
EU 1	Merve 1	<65			G1	

a) Where possible ventilation dampers, filters and other services will be designed and positioned so that they are accessible from *outside* the manufacturing areas (service voids or service corridors) for maintenance purposes.

b) Directional airflow within production or primary packaging areas will assist in preventing contamination. Airflows will be planned in conjunction with operator

locations, so as to minimize contamination of the product by the operator and also to protect the operator from dust inhalation.

c) HVAC air distribution components will be designed, installed and located to prevent contaminants generated within the room from being spread.

c) Air diffusers will be selected with care taking consideration of, e.g. room requirements and positions of equipment and operators in the room. Supply air diffusers of the high induction type (e.g. those typically used for office-type air-conditioning) will where possible not be used in clean areas where dust is liberated. Air diffusers will be of the non- induction type, introducing air with the least amount of induction so as to maximize the flushing effect.

Pressure differential concept (high pressure differential, low airflow)

a) The high pressure differential between the clean and less clean zones will be generated by
leakage through the gaps of the closed doors. The pressure differential will be of sufficient magnitude to ensure containment and prevention of flow reversal, but will not be so high as to create turbulence problems.

b) Considering room pressure differentials, transient variations, such as machine extract systems, will be taken into consideration.

c) A pressure differential of 15 Pa is often used for achieving containment between two adjacent zones, but pressure differentials of between 5 Pa and 20 Pa may be acceptable. Where the design pressure differential is too low and tolerances are at opposite extremities, a flow reversal can take place. For example, where a control tolerance of ± 3 Pa is specified, the implications of rooms being operated at the upper and lower tolerances will be evaluated. It is important to select pressures and tolerances such that a flow reversal is unlikely to occur.

d) The pressure control and monitoring devices used will be calibrated and qualified **(Exhibit Z)**. Control systems, where used, will be set up during commissioning, with set point marked, and will not change unless other system conditions change. Pressure control devices will be linked to an alarm system set according to the levels determined by a risk analysis.

e) An Airlock will be set up between the shipping bay and packaging area in order to maintain a pressure cascade systems to limit cross-contamination of outside adulterants from entering the packaging area.

f) An airlock is defined as “an enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered.”

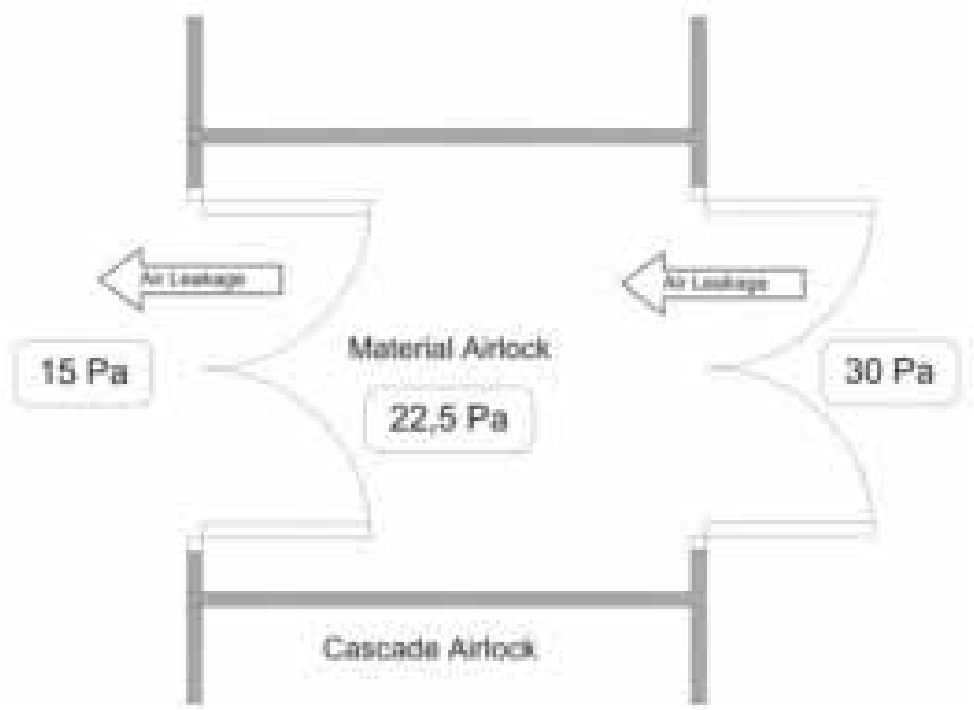
g) A cascade airlock **(Exhibit AA)** will be utilized in which higher pressure is on one side of the airlock and lower pressure on the other; the door will open to the high pressure side, so that room pressure assists in holding the door closed and in addition be provided with self- closers. The doors will open to the low pressure side, the door closer springs will be sufficient to hold the door closed and prevent the pressure differential from pushing the door open.

h) Material pass-through-hatches (PTH) will be used between the tissue culture room and open cultivation area where separate air-quality and air-pressure are present between the two areas.

Exhibit Z: Pressure Gauge Reader

Image of room pressure gauge indicating colour coded normal, alert & action parameters

Exhibit AA: Cascade airlock



a) Where appropriate, temperature and relative humidity will be controlled, monitored and recorded, where relevant, to ensure compliance with requirements pertinent to the materials and products and provide a comfortable environment for the operator where necessary.

b) Alert and action limits on temperatures and humidity's will be set, as appropriate.

c) The operating band, or tolerance, between the acceptable minimum and maximum temperatures will not be made too close. Tight control tolerances may be difficult to achieve and can also add unnecessary installation and running costs.

d) The drying rooms where low relative humidity is needed, will have well-sealed walls and ceilings and will also be physically separated from adjacent areas with higher relative humidity

e) Precautions will be taken to prevent moisture migration that increases the load on the HVAC system.

f) Humidity control will be achieved by removing moisture from the air, or adding moisture to the air, as relevant.

g) Dehumidification (moisture removal) will be achieved by means of refrigerated dehumidifiers. Appropriate cooling media for dehumidification such as refrigerant will be used.

h) Humidifiers will be avoided as they may become a source of contamination (e.g. microbiological growth). Where humidification is required, this will be achieved by appropriate means such as the injection of steam into the air stream. A product-contamination assessment will be done to determine whether pure or clean steam is required for the purposes of humidification.

i) Humidification systems will be well drained. No condensate will accumulate in air-handling systems.

j) Humidification appliances such as evaporative systems, atomizers and water mist sprays, will not be used in the Processing Center because of the potential risk of microbial contamination.

k) Air filters will not be installed immediately downstream of humidifiers, as moisture on the filters could lead to bacterial growth.

l) When specifying relative humidity, the associated temperature will also be specified.

Design of HVAC systems and components

a) The required degree of air cleanliness in most OSD manufacturing facilities can normally be achieved without the use of high-efficiency particulate air (HEPA) filters, provided the air is not recirculated.

b) A risk assessment will be carried out to determine the cleanroom conditions required and the extent of validation required.

c) There are two basic concepts of air delivery to pharmaceutical production facilities: a recirculation system, and a full fresh air system (100% outside air supply).

d) The center will employ recirculation system because 100% fresh air and would normally be used in a facility dealing with toxic products or solvents, which the center will not since CO2, ethanol, and glycol alcohol are not designated as toxic solvents

e) For recirculation systems the amount of fresh air will not be determined arbitrarily on a percentage basis, but, for example, by the following criteria:

1. sufficient fresh air to compensate for leakage from the facility and loss through exhaust air systems;
2. sufficient fresh air to comply with national building regulations; and
3. sufficient fresh air for odor control.

f) Where automated monitoring systems are used, these will be capable of indicating any out-of-specification condition without delay by means of an alarm or similar system. Sophisticated computer-based data monitoring systems may be installed, which can aide with planning of preventive maintenance and can also provide trend logging. This type of system is commonly referred to as a building management system (BMS). Since these systems are used for critical decision-making, they will be validated.

g) Failure of a supply air fan, return air fan, exhaust air fan or dust extract system fan can cause a system imbalance, resulting in a pressure cascade malfunction with a resultant airflow reversal.

h) All critical alarms will be easily identifiable and visible and/or audible to relevant personnel.

i) Appropriate alarm systems will be in place to alert personnel if a critical fan fails. A fan interlock failure matrix will be set up, such that if a fan serving a high pressure zone fails, then any fans serving surrounding lower pressure areas will automatically stop, to prevent an airflow reversal and possible cross-contamination.

Commissioning, qualification and maintenance

a) Commissioning will include the setting up, balancing, adjustment and testing of the entire HVAC system, to ensure that it meets all the requirements, as specified in the user requirement specification (URS), and capacities as specified by the designer or developer. The commissioning plan will start at the early stages of a project so that it can be integrated with qualification and verification procedures.

b) The installation records of the system will provide documented evidence of all measured capacities of the system.

c) Acceptance criteria will be set for all system parameters. The measured data will fall within the acceptance criteria.

d) Acceptable tolerances for all system parameters will be specified prior to commencing the physical installation.

e) Training will be provided to personnel after installation of the system, and will include operation and maintenance.

f) Commissioning will be a precursor to system qualification and process validation.

Qualification

a) A risk-based approach will be used to identify the extent to which the HVAC system

requires qualification and verification. The basic concepts of qualification of HVAC systems are set out below.

b) Critical and non-critical parameters will be determined by means of a risk analysis for all HVAC installation components, subsystems and controls.

c) Any parameter that may affect the quality of the pharmaceutical product, or a direct impact component, will be considered a critical parameter. All critical parameters will be included in the qualification process.

d) A realistic approach to differentiating between critical and noncritical parameters is required, to avoid making the validation process unnecessarily complex.

e) For a pharmaceutical facility, based on a risk assessment, some of the typical HVAC system parameters that will be qualified may include:

1. relative humidity
2. temperature
3. supply air quantities for all diffusers
4. return air or exhaust air quantities
5. room air change rates
6. room pressures (pressure differentials)
7. room airflow patterns
8. unidirectional flow velocities
9. containment system velocities
10. HEPA filter penetration tests
11. room particle counts
12. room clean-up rates
13. microbiological air and surface counts where appropriate
14. operation of de-dusting
15. warning/alarm systems where applicable.

f) **Exhibit BB** gives various tests that can be carried out to test parameters. The required tests and intervals between testing will be determined through risk assessment.

Exhibit BB: Tests to demonstrate compliance

Test parameter	Test procedure
Particle count test (Verification of cleanliness)	Dust particle counts to be carried out and result printoutsproduced. No. of readings and positions of tests to be in accordancewith ISO 14644-1

Air pressure difference (To verify non cross-contamination)	Log of pressure differential readings to be produced or critical plants will be logged daily, preferably continuously. A 15 Pa pressure differential between different zones is recommended. In accordance with ISO 14644-3
Airflow volume (To verify air change rates)	Airflow readings for supply air and return air grilles to be measured and air change rates to be calculated. In accordance with ISO 14644-3
Airflow velocity (To verify unidirectional flow or containment conditions)	Air velocities for containment systems and unidirectionalflow protection systems to be measured. In accordance with ISO 14644-3
Filter leakage tests (To verify filter integrity)	Filter penetration tests to be carried out by a competent person to demonstrate filter media, filter seal and filter frame integrity. Only required on HEPA filters. In accordance with ISO 14644-3
Containment leakage (To verify absence of cross-contamination)	Demonstrate that contaminant is maintained within a room by means of: • airflow direction smoke tests • room air pressures. In accordance with ISO 14644-3
Recovery (To verify clean-up time)	Test to establish time that a cleanroom takes to recover from a contaminated condition to the specified cleanroom condition. Will not take more than 15 min. In accordance with ISO 14644-3
Test parameter	**Test procedure**

Airflow visualization (To verify required airflow patterns)	Tests to demonstrate air flows: • from clean to dirty areas • do not cause cross-contamination • uniformly from unidirectional airflow units Demonstrated by actual or video-taped smoke tests. In accordance with ISO 14644-3.

g) Clean-up or recovery times normally relate to the time it takes to "clean up" the room from one condition to another, e.g. the relationship between "at- rest" and "operational" conditions in the clean area will be used as the criteria for clean-up tests. Therefore, the clean-up time can be expressed as the time taken to change from an "operational" condition to an "at rest" condition.

h) Energy-saving procedures such as reducing the airflow during non-production hours are used, precautionary measures will be in place to ensure that the systems are not operated outside the defined relevant environmental conditions.

i) These precautionary measures will be based on a risk assessment to ensure that there is no negative impact on the quality of the product.

j) That will be included in the qualification manuals will include system airflow schematics, room pressure cascade drawings, zone concept drawings, air-handling system allocation drawings, particle count mapping drawings, etc.

Maintenance

There will be a planned preventive maintenance program, procedures and records for the HVAC system. Records will be kept.

a) Operation and maintenance (O&M) manuals, schematic drawings, protocols and reports will be maintained as reference documents for any future changes and upgrades to the system. These documents will be kept up to date, containing any system revisions made.

b) Maintenance personnel will receive appropriate training.

c) PA filters will be changed either by a specialist or a trained person, and then followed by installed filter leakage testing.

d) Any maintenance activity will be assessed critically to determine any impact on product quality including possible contamination.

e) Maintenance activities will normally be scheduled to take place outside production hours, and any system stoppage will be assessed with a view to the possible need for requalification of an area as a result of an interruption of the service.

1.2 Genetic Sourcing

Plants for production come from three sources: seed, clone or tissue culture. Seeds are naturally 50/50 male and female, but some companies now specialize in feminization, where they guarantee all female plants[1]. A clone is a cutting from one mother plant that is rooted and allowed to grow into a self-sufficient plant. Clones are genetically identical to the plants from which they were cut.[2]. Marijuana cultivars grown by asexual propagation under controlled environmental conditions could be accurately distinguished based on their cannabinoid and terpenoid profiles. By using these methods we keep the final product true to its form, DNA of the plants is replicated not transferred through pollination. Special care will always be taken to ensure that the mother plants are in good health which will ensure the DNA of the plants goes unaltered.

Tissue culture is the process of cutting a small amount of tissue from a plant and put into a petri dish (or test tube) where it can be stored for years, cleansed of disease, and duplicated into another identical plant. This process will be within a HEPA filtered clean room lab under aseptic conditions. The result in theory is genetically the same as a clone, but with purification and less chance of genetic degradation[3]. Once this technique is perfected it will be possible to further standardize the chemical content of cannabinoid profile as well as terpenoid profile when cultivated in our company's pharmaceutically modeled cultivation environment. All of the infrastructure will be in place for the company to utilize only tissue culture specimens to populate the greenhouse, however, because of the logistical difficulties presented by tissue culture, it will take a year or more before this technique can be utilized at the commercial scale. Therefore, seeds will be utilized to initially populate the greenhouse until clone providing mother plants can be created and further replicated through the in-vitro propagation program.

Mother rooms, seed stock, and tissue culture labs can be a source of contamination. A contaminated plant transferred from the propagation area to the production area could transmit contaminants to the rest of the crop. It also may be genetically weak and draw undesired attention from pests to an otherwise healthy crop. In order to prevent spread of contamination and the contamination itself all plants will be inspected and treated as necessary prior to moving from one cultivation area to another. If a plant is found to be infected to a point that is irreversible that plant will be thrown away, rendered unusable, and noted in the inventory management system. If a plant is found to have an issue that is reversible then special care will be taken to treat this plant and quarantined if necessary. The HVAC systems as well as the facility layout will provide a mechanism in itself of preventing contamination and spread of unwanted organisms in the crop. Beyond this all cultivation areas will be cleaned regularly and thoroughly ensuring special care is given to remove any plant debris which may harbor unwanted disease or insects.

1.3 Strain Selection

To treat a wide range of the current qualifying chronic diseases The Company will produce a wide variety of marijuana strains with varying ratios of THC and CBD levels (the two most influential cannabinoids). We detail the different profile levels and the corresponding diseases they are best suited to treat in the figure below.

Target Therapeutic Group for Different Ratios

Product group	Ratio THC: CBD	Target Therapeutic Area
High THC	**>95:5**	**Cancer pain, Migraine, Appetite, Stimulation**
Even ratio	**50:50**	**Multiple sclerosis, Spinal cord injury, Peripheral neuropathy, other neurogenic pain**
Reverse/Broad	**CBD <25:75**	**Rheumatoid arthritis and Inflammatory bowel diseases**
High CBD		**Psychotic disorders (schizophrenia), Epilepsy & movement disorders, Stroke, head injury, Disease modification in RA and other inflammatory conditions, Lupus, and Appetite suppression**

Flowering Zone	Component	Data	Medicinal Treatment (Anecdotal)
1	Strain	Grape Ape	This strain is able to treat those suffering from loss of appetite, insomnia, chronic or debilitating pain. Provides intense stress relief. Specifically good for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	High THC	
	Type	Granddaddy Grape (which was a phenotype of Granddaddy Purple) x Skunk #1	
	THC %	20 -24 %	
	CBD	1.09%	
	CBN	2.10%	
	Flowering State	56 days after flower initiation	
2	Strain	Tahoe OG KUSH	This strain is able to treat those suffering from loss of appetite, insomnia, chronic or debilitating pain. Provides intense stress relief. Specifically good for Illinois approved qualified conditions where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	(SFV OGK F3 x OG KUSH)	
	Type	Indica	
	THC %	20 – 24%	
	CBD	0.21%	
	CBN	0.53%	
	Flowering State	70 days after flower initiation	
3	Strain	OG KUSH #18	This strain is highly useful for combating symptoms of Alzheimers' as well mitigate effects of migraine headaches, vomiting, depression, Parkinson's disease, chronic pain, AIDS, cancer, and rheumatoid arthritis.
	Genetics	(Chemdawg x Lemon Tai)	
	Type	Hybrid Sativa heavy	
	THC %	20 – 24%	
	CBD	0.25%	
	CBN	0.11%	
	Flowering State	72 days after flower initiation	

1.3.2 Strain Selection

4	Strain	Lemon Diesel	This strain is ideally for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	California Sour (Mexican sativa x Afghan) Mother x Lost Coast OG Kush	
	Type	Indica Heavy	
	THC %	20 – 24%	
	CBD	0.23%	
	CBN	0.53%	
	Flowering State	70 days after flower initiation	
5	Strain	818 headband (Sour OG Kush)	This strain is able to treat those suffering from loss of appetite. Specifically good for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	(Original Sour Diesel x SFV OGK IBL)	
	Type	Indica & Sativa	
	THC %	20 – 24%	
	CBD	0.21%	
	CBN	0.53%	
	Flowering State	70 days after flower initiation	
6	Strain	Girl Scout Cookies	Therapeutic medicinal effect capable of relieving pain, neuropathy, and muscle spasms.
	Genetics	(OG Kush x Cherry Pie x Durban Poison)	
	Type	Hybrid Indica	
	THC %	25 – 30%	
	CBD	0.21%	
	CBN	0.53%	
	Flowering State	63 days after flower initiation	
7	Strain	Blue Dream	This strain is able to treat those suffering from loss of appetite, insomnia, chronic or debilitating pain. Provides intense stress relief. Specifically good for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	Blueberry x Haze	
	Type	Hybrid which is Sativa dominant	
	THC %	20 – 24%	
	CBD	Up to 1%	
	CBN	0.05%	
	Flowering State	68 days after flower initiation	
8	Strain	Purple Diesel	This strain provides patients suffering from lethargy and drowsiness boost of energy and help uplift as well and mitigate depression symptoms.
	Genetics	(Purple Kush x Sour Diesel)	
	Type	Sativa	
	THC %	18%	
	CBD	0.55%	
	CBN	0.72%	
	Flowering State	55 days after flower initiation	
9	Strain	Lambs Bread	This strain is ideal for disorders effecting a patient's mental condition and any pain specifically located in the cranium region such as traumatic brain injury or post-concussion syndrome
	Genetics	Jamaican Sativa	
	Type	Sativa	
	THC %	20 – 24%	
	CBD	0.61%	
	CBN	0.37%	

4	Strain	Lemon Diesel	This strain is ideally for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	California Sour (Mexican sativa x Afghan) Mother x Lost Coast OG Kush	
	Type	Indica Heavy	
	THC %	20 – 24%	
	CBD	0.23%	
	CBN	0.53%	
	Flowering State	70 days after flower initiation	
5	Strain	818 headband (Sour OG Kush)	This strain is able to treat those suffering from loss of appetite. Specifically good for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	(Original Sour Diesel x SFV OGK IBL)	
	Type	Indica & Sativa	
	THC %	20 – 24%	
	CBD	0.21%	
	CBN	0.53%	
	Flowering State	70 days after flower initiation	
6	Strain	Girl Scout Cookies	Therapeutic medicinal effect capable of relieving pain, neuropathy, and muscle spasms.
	Genetics	(OG Kush x Cherry Pie x Durban Poison)	
	Type	Hybrid Indica	
	THC %	25 – 30%	
	CBD	0.21%	
	CBN	0.53%	
	Flowering State	63 days after flower initiation	
	Flowering State	73 days after flower initiation	
10	Strain	LA Confidential	Extremely helpful to treat spastic ailments such as Multiple Sclerosis, Parkinson's Disease, Spinal Cord Injury, Amyotrophic Lateral Sclerosis (ALS), and Epilepsy.
	Genetics	O.G. LA AFFIE x Afghani	
	Type	100% indica	
	THC %	24 – 27%	
	CBD	0.20%	
	CBN	0.15%	
	Flowering State	69 days after flower initiation	
11	Strain	Charlotte's Webb	Extremely helpful to treat spastic ailments such as Multiple Sclerosis, Parkinson's Disease, Spinal Cord Injury, Amyotrophic Lateral Sclerosis (ALS), and Epilepsy. This high CBD strain is also useful for Lupus and Rheumatoid arthritis
	Genetics		
	Type	Sativa	
	THC %	0-5%	
	CBD	15-20%	
	CBN	0-10%	
	Flowering State	55 days after flower initiation	
12	Strain	The Cornerstone	Extremely helpful to treat spastic ailments such as Multiple Sclerosis, Parkinson's Disease, Spinal Cord Injury, Amyotrophic Lateral Sclerosis (ALS), and Epilepsy. This high CBD strain is also useful for Lupus and Rheumatoid arthritis
	Genetics		
	Type	Sativa	
	THC %	0 – 10%	
	CBD	15 – 20%	
	CBN	0.53%	
	Flowering State	55 days after flower	

4	Strain	Lemon Diesel	This strain is ideally for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	California Sour (Mexican sativa x Afghan) Mother x Lost Coast OG Kush	
	Type	Indica Heavy	
	THC %	20 – 24%	
	CBD	0.23%	
	CBN	0.53%	
	Flowering State	70 days after flower initiation	
5	Strain	818 headband (Sour OG Kush)	This strain is able to treat those suffering from loss of appetite. Specifically good for ailments where stress can cause chronic pain such as , severe fibromyalgia, spinal cord disease, including but not limited to arachnoiditis, Tarlov cysts, hydromyelia, syringomyelia, spinal cord injury, Reflex Sympathetic Dystrophy, RSD (Complex Regional Pain Syndromes Type I), Causalgia, CRPS (Complex Regional Pain Syndromes Type II)
	Genetics	(Original Sour Diesel x SFV OGK IBL)	
	Type	Indica & Sativa	
	THC %	20 – 24%	
	CBD	0.21%	
	CBN	0.53%	
	Flowering State	70 days after flower initiation	
6	Strain	Girl Scout Cookies	Therapeutic medicinal effect capable of relieving pain, neuropathy, and muscle spasms.
	Genetics	(OG Kush x Cherry Pie x Durban Poison)	
	Type	Hybrid Indica	
	THC %	25 – 30%	
	CBD	0.21%	
	CBN	0.53%	
	Flowering State	63 days after flower initiation	
13	Strain	Harlequin	Extremely helpful to treat spastic ailments such as Multiple Sclerosis, Parkinson's Disease, Spinal Cord Injury, Amyotrophic Lateral Sclerosis (ALS), and Epilepsy. This high CBD strain is also useful for Lupus and Rheumatoid arthritis
	Genetics		
	Type	Sativa	
	THC %	0 – 5%	
	CBD	17%	
	CBN	0.53%	
	Flowering State	55 days after flower initiation	

1.4 Cultivation Controls

1.4.1 Environmental Control System

The heart of the control of the total facility will be a Priva BMS Blue ID computer. The facility will require a very extensive control program given the complexity of control that is required. The choice for BMS versus the standard horticulture solutions is for the following reasons:

- Bespoke programming is available so that it can be tailored specifically to our facility
- Extensive use of graphics allow for an easy operator interface
- The use of BMS allows for very high level of interactive design interfaces
- Licensing costs are cheaper than those for a more rigid structure that exists within the Priva Hort Products. Also rather than having to adapt programs as would be the case with a Priva Hortisystem, the Priva BMS allow fully-bespoke programs to be developed.
- Installation for communication between the Host PC and remote control / access points can be daisy chained with a simple pair of cables as opposed to wiring many I/O's back to a central location
- The use of the Priva BMS system will allow a local Priva Partner to support an installation. We have been advised against in-house PLC control because of the dependence on the programming organization, creating vulnerability, and the precise and inflexible nature of the program.

The BMS system consists of a series of networked controllers that share the common information. These controllers all report back to a supervisory PC, where the operator can see the state and operation of the whole installation through an easy-to-use graphical interface. The supervisory PC will run "TC-integration". This software package not only gives a graphical representation of the equipment controlled by the Priva BMS but also allows integration with third-party equipment, such as CCTV. Therefore, a live image of the process can be superimposed with the BMS controls associated with it. TC-Integration also allows equipment from other vendors to be integrated, so the software can evolve as the facility develops and requirements change.

The controlled indoor cultivation area temperatures and lighting conditions will be controlled by a Priva control system. Chilled air will be supplied via a rapidly responding air handling system to ensure that a target temperature is achieved within a +/- 3F differential. Lighting will be programmed to turn on at the desired times of the day to control photoperiod. Lastly Decagon sensors can monitor the temperature, humidity, and CO2 levels. Photoperiod sensors can monitor the canopy level Daily light integral (light levels) provided by the lighting. In addition Decagon substrate sensors can monitor individual plant's root temperature, water pH, and nutrient levels.

1.4.2 Climate

To ensure quality control and healthy plant growth, proper environmental conditions including air temperatures, humidity, and root zone temperatures will be maintained through all cultivation stages. Healthy plants with strong immune systems have higher resistance to pests and disease, and therefore require fewer adulterants and as a result are less likely to acquire natural contaminants. Throughout the production lifecycle there are a few benchmark conditions at each stage of development. Below lists in order the target temperature and relative humidity of the cultivation area for each process. A temperature differential of no more than +/- 3 degrees will be maintained at all times **(Exhibit B)**.

The growth chamber was designed with a series of relatively small zones to provide more climate control capacity. To maintain this high level of climate control in the hybrid greenhouse zones, an evaporative cooling system combined with a supplemental HVAC system will be installed to insure near exact climate control 12 months per year no matter what the weather is outside. The filtered HVAC system will be used to control the climate of all non-greenhouse rooms and areas as well.

Storage of products used for marijuana cultivation also require a specific climate. For example, beneficial bacteria, beneficial insects, and microbial teas all have optimal temperature and humidity ranges. If the proper conditions are not met, aerobic bacteria can turn anaerobic and cause disease. Products can spoil and grow mold. Sanitation and cleaning chemicals will be isolated in their own janitorial closet to prevent cross contamination of plant nutrients.

1.4.3 Crop Layout

The propagation area will be outfitted with rolling benches. This will facilitate an efficient use of space and allow batches and/or strains to be kept separate for purposes of sanitation. For each square foot of useable bench space the propagation tables will hold approximately 25 seedlings/clones.

The vegetative growing areas will also be outfitted with rolling benches. This will facilitate an efficient use of space and allow batches and/or strains to be kept separate for purposes of sanitation. For each sq. ft. of useable bench space the vegetative tables will hold approximately 4 juvenile plants.

The flowering growing areas will be outfitted with hanging gutters this will provide ideal crop concentration while maintaining four foot of separation between gutters. This four-foot spacing would create plant canopies just touching at maturity between rows and proper planting density will create plant canopies just touching at maturity within rows. Each flowering plant will take up approximately 25 sq. ft. of the usable greenhouse space. This arrangement ensures workers can easily get to all areas of the plants and that all the useable growing space is utilized further ensuring the supply chain.

1.4.3 Plant Stress

Due to its illegality and value, marijuana has been grown under conditions that no legal consumable plant would ever be subjected. There is a threshold where the plant can become vulnerable to pest and disease due to stress. Many high-performing marijuana gardens fall prey to pests and disease simply because the conditions are too intense, thus weakening the immune responses of the plants. Measuring the stress on a plant requires subtle observations of the plant's general health and knowledge of what historical stressors the plant is still carrying. Color, vascular pressure, the orientation of the leaves as they track the light, water consumption, fertilizer consumption, growth rate, stem diameter, and plant structure are all indicators of general plant health. The company will utilize automated fertigation systems coupled with a series of digital sensors to ensure plants receive the precise the amount of water, nutrients, CO2, and light need to optimize each individual cultivar.

1.4.4 Plant Health

Air flow is principally important for proper transpiration and prevention of a hospitable environment for pests to develop. A strong air-flow pushing against the plant forces it to build branch strength resulting in healthier plants. The Company has designed the controlled environment with air handling units to ensure even consistent air flow throughout each cultivation zone.

How the plants are arranged, pruned, and trained plays a role in the airflow through the plant canopy. Typically, pests will start on a weak plant and travel as their populations and colony matures, so it is very important to have individual plant inspection and quarantines.

1.4.5 Integrated Pest Management (IPM)

1. Adequate pest control will be provided.

a. Animals or pests will not be allowed in any area of the facility, except that guard or guide dogs may be allowed in some areas of the facility if the presence of the dogs will not result in contamination of components, packaging components, in-process materials, marijuana or marijuana-derived products, or contact surfaces;

b. Effective measures will be taken to exclude pests from the facility and to protect against contamination of components, packaging components, in-process materials, marijuana or marijuana-derived products, and contact surfaces on the premises by pests; and

c. Insecticides, fungicides, or rodenticides will not be used in or around the facility, unless they are registered with EPA and used in accordance with the label instructions, and effective precautions are taken to protect against the contamination of components, packaging components, in-process materials, marijuana or marijuana-derived products, or contact surfaces.

IPM is an integrated system if monitors and controls used as a means to understanding pest threats and developing a proper prevention plan. The UN's Food and Agriculture Organization defines IPM as "the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment." IPM emphasizes the growth of a healthy crop with the least possible disruption to agro ecosystems and encourages natural pest control mechanisms."

1.4.8 Yield vs. Health

Healthy plants have strong immune responses and require far less if any chemical intervention. Naturally, marijuana cultivators strive for high yields, however pushing the plant to produce a higher yield can add stress and may result in lower quality. Many cultivators 'push' their plants with heavy fertilization, special additives, foliar feeding, extra lighting, enriched carbon dioxide, extra water, aggressive pruning and training, and high transpiration rates. These techniques may result in higher yields but may degrade the finished product. The health of the plant has a direct relationship with quality as it will only grow to its true genetic potential if it is vigorous. The company will strive to keep the plant's life path as close to its natural state while gently optimizing its growth environment to create an optimal balance between maximum yield and avoiding the presence of artificial adulterants in the final product.

1.5 Cultivation Plan

The company intends to employ a team of expert growers and scientists, as well as train the support staff to the fullest extent practical. We intend to build a pharmaceutically modeled manufacturing facility which will employ high tech solutions to supply safe, high quality, uniform products. We will offer a wide array of solutions for all qualifying patients and the key to maintaining our supply of these products will be planning.

We have hired experts in plant production with years of experience maintaining a plant supply chain. We also have in our employ a consultant whom has the expert specialized knowledge required to know the subtleties of each plant, growing environment and processes to complete the seed to sale loop and consistently solve any problems which may arise.

Because of our highly skilled team the plan will be executed in a reverse engineering process. We will plan the first harvest on the earliest possible track to provide high quality products to market. This early first harvest will strictly be based on licensing and regulation compliance to begin production as soon as our facility is approved for production by the state.

1.6 Product Flow Overview

To reduce the risk of contamination increases to a developing plant and the product an efficient product flow is key. This has lead the company to design a scalable commercial facility; this will prevent contamination of younger material by older material as well as allow for efficient movement of plants and product without any chance of process bottle necks. As demonstrated in detail in the cultivation plan, the tightly climate controlled growth chambers in the cultivation facility will handle all plant propagation and plant testing. These chambers will be completely isolated from outdoor exposure.

Additionally, Mother plants will be isolated from younger plants in its own growth chamber, this will protect against the risk that they could spread any acquired disease. The growth chamber will allow newly finished propagation plants to exit the head house area in batches of 1,200 plants free of pests, diseases and fungus, these will be tagged with a unique RFID tag prior to leaving the propagation area. The plants will be moved to the individual vegetative zones without ever passing through the flowering zones in order to not compromise older plants which may be more susceptible to contamination. As the plant matures to the desired height, it will be moved into a flowering zone, where once fully mature and ripened will be harvested and physically flow "downstream" to each of the compartmentalized, secure rooms quickly and efficiently to prevent mold and fungus from developing.

Trimming will occur once the plants are removed from the growth areas and will consist of mechanical trimmers to remove large fan leaves and unusable leaf material. All fine leaves, sepals, will be left and removed with the buds and bottled for freezing. Specialized laborers designated as trimmers will manually pull the plant material from the stems by hand and with scissors. The bare branches will be placed in bins marked for waste. The buds and sepals will be placed into a 2.5 gallon glass apothecary jar to be stored in the designated freezing section of the climate controlled vault.

From propagation to the secure shipping bay, all compartmentalized rooms will be equipped with automated "State Selected Software" compatible RFID sensors above the doorway to automatically track each plant and gram throughout the entire manufacturing process.

Redacted pursuant to N.Y. Public Officers Law, Art. 6

Section 2: Transport and Distribution

Redacted pursuant to N.Y. Public Officers Law, Art.6

Section 3: Dispensing and Sale

3.1 Overview

Kinex Supportive Pharmaceuticals believes that a balance can be struck between a secure welcoming patient care environment and a high level of security. Our design guidelines, patient counseling protocols, and security operations are all created to reflect our commitment to the patient experience.

This experience will potentially be disorienting to our patient base, and our role is to provide them with a safe and secure environment to familiarize themselves with a new therapeutic alternative. We refer to this as the "patient journey". The patient journey involves significant barriers to accessing this therapy. While it has not been completely articulated from the state as to how Kinex Supportive Pharmaceuticals can intercede on a patients behalf, we will be working with DOH to establish clear areas where as a company we can decrease the barriers to access. Examples could include such things as Compliance and Adherence programs, financial assistance, and future delivery options. Our commitment as a pharmaceutical company is to ensure the patient receives the right drug, at the right time and with the proper understanding of the therapeutic value.

Our dispensary operations will be built and operated based on the NYS Pharmacy board retail pharmacy license. We intend to apply the "Department within" rules when designing our dispensary's to allow for the most flexibility for our operations. This will allow for security personal to open and secure the facility prior to the Pharmacist (PIC) or supervising pharmacist to open the facility. Additionally the facility can remain secure with dispensing services shut down when the pharmacist would need to step out, a very common occurrence in pharmacy operations today in NYS.

Our dispensary team will be led by our COO who has developed a number of successful specialty pharmacies in the U.S., and two ongoing SP's in NY. His understanding of the NY pharmacy laws and how they can be applied to this new venture will be helpful in working with the DOH, and the board of Pharmacy when Pharmacists are involved. We understand the nuances of the pharmacists role in this social experiment and will work to ensure compliance at all times with all involved regulatory agencies.

3.2 Operations- Opening and Closing procedures

Dispensary management starts with employee safety. So before leaving for work, the security guard will securely log into the Company's security system to view a fast-forward rendering feed from all strategically located cameras running 24/7 throughout the inside areas of the dispensary and the dispensary parking lot. Full visual access will be available on the security guard's smart phone, home computer, or digital tablet. Video data captured and reviewed will be from the last store-closing day/time to present time.

The security guard will arrive at the Company's dispensary 45- 60 minutes before

opening to prepare for the day. He/she will check all areas for any disturbances; make sure the premises are clean and tidy, and review the daily operations email from our Director of Security.

A Pharmacist will arrive 15-30 minutes before opening. Together, the security guard and Pharmacist will access the Restricted Access Area (Restricted access Area) and pull the cash drawer(s). Together the security guard and pharmacist will count and verify the cash and then place it in the point-of-sale (POS) cash register.

The remaining dispensary staff if any: cashier, receptionist additional security guard, etc., will all arrive 15 minutes before opening.

Closing procedures will involve returning all cannabis products to the secure storage area if they have been brought out by pharmacist, transferring all cash proceeds to the dispensaries vault inside the Restricted access Area, cleaning the dispensary, and activating all alarm systems prior to leaving the dispensary.

3.3 Patient Engagement

Our patient-verification system will be handled by the "State Selected Software" software system, a powerful tool for tracking patients, purchases, and more. Once a patient is logged into "State Selected Software", all pertinent records will be on file, and only current card-carrying patients will be permitted to purchase product. This is ensured through "State Selected Software's" patient check-in feature. The system automatically looks for expired documentation upon patient arrival.

Furthermore, the system will allow the Company's employees to notify patients with expired or soon-to-be-expired documentation via email or text message.

Purchases will be processed through "State Selected Software's" point of sale (POS) system, as follows:

(1) Prior to entrance to the dispensary, and then again at the sale of medical cannabis to a patient, the Security Staff, and then pharmacist will physically inspect the patient's driver's license (or state issued ID), verify the identity of the patient and confirm the validity of the card; (2) The Pharmacy Technician shall then go to the patient Management Page of the "State Selected Software" system and pull up the applicable patient profile by entering the patient's name, driver's license, or registration number; (3) If the patient's name or driver's license is not found in the System's patient Profile page, the Pharmacist will create a new patient Profile; (4) If the "State Selected Software" System flags any patient with invalid information showing on his/her patient Profile, the log-in will terminate. If a patient is flagged, the System notifies the agent as to which information is invalid so it can be corrected (if possible); (5) In the event that the patient is unqualified, invalid, or banned and the System blocks the sales process, the agent will notify the patient of the reasons for the denial of the sale, and offer suggestions for compliance (if available); (6) In the event the System permits the transaction, the cashier will pull up the patient's information from the POS and begin the transaction. The POS will include a list of the customer's previous purchases, as well as symptoms, ailments, or disabilities; (7) The POS system will also assure compliance with regulatory controls and limitations placed on patient cannabis acquisition and will verify that the amount of product the patient or designated primary

caregiver is requesting does not exceed the time allowances under NYS law; (8) The pharmacist will enter the following information directly into the POS database: (i) name and number of the registry identification card of the patient or of the designated primary caregiver of the patient; (ii) the amount of the medical cannabis dispensed; (iii) whether the medical cannabis was dispensed to the patient or to the designated caregiver; (iv) the date and time at which the medical cannabis was dispensed; (v) the number of the medical cannabis dispensary registration and (9) The pharmacist will then process the order, retrieve the product and provide it to the patient. ***(NOTE: It is unclear in the application as to whether a pharmacist can hand the patient the product. Clarifying discussions with DOH and BOP will need to be initiated to determine pharmacist restrictions)***

All patient records, including demographic information; registry number and expiration date; limitations on purchases; purchases and denials of sale, and other pertinent information will be maintained on the "State Selected Software" system. Once a patient's record is created in that system, any subsequent modification must be logged with details of the changes made, username, and timestamp. State-issued identification cards, recommendations, intake forms, and all paperwork relating to the intake process will be attached to each patient profile for easy viewing at any time. All such information will be kept strictly confidential and will be stored in accredited, HIPPA- compliant servers. The System contains comprehensive protections for patient privacy and confidentiality of patient information. All patients will be advised of their right to confidentiality, including rights under The Health Insurance Portability and Accountability Act of 1996 (HIPAA), to include the Hitech act, additionally the company will have all applicable privacy forms reviewed and executed by each patient

3.4 Storage and Handling within the Dispensary

Several 12-inches x 12-inch signs with 1 -inch lettering will be posted on the wall area outside the Restricted access Area room and on the Restricted access Area wall. Signs will say, "Do Not Enter, Restricted Access Area to Authorized Personnel Only."

The pharmacist will manage all Restricted Access Area functions, including cultivation center delivery of product, manifest recording and reconciliation, and inputting all receipts into the "States Selected Software" inventory system. Once the product, dose, delivery system, and quantity is determined and agreed upon, the pharmacist will bring product into the dispensing room. The pharmacist will be the Company's primary

employee who will access the Restricted access Area and vaults and bring cannabis-based product from the Restricted access Area to the Pharmacist or Pharmacist Technician to fulfill purchase orders. Purchase orders which will be delivered through a secure pass-through from the Restricted access Area to the Pharmacist or Pharmacist Technician area. The Pharmacist is responsible for confirming that the correct product is brought from the Restricted access Area to the Dispensing room and that it matches the order generated.

Upon sale of the product to the patient, the Pharmacist or Pharmacist Technician will enter and digitally sign this transaction into "States Selected Software's" patient log and inventory system. The patient will receive a receipt generated by the "States Selected Software" system showing the following "prescription" information: patient name, address, prescription number, date, time, brand, type (Sativa, Indicia, hybrid), dosage form, quantity (milligrams, milliliters, total weight/active ingredient weight), chemical content and percentage (e.g., THC 8%, CBD 43% CBN 2%, THCA 6.5%, etc.), dosing directions, doctor's name and phone number, refill quantity remaining per 2-week limit, retail price, company's name/logo, address and phone number, the manufacturer (cultivation center registry number), educational content (uses, effects, warnings, and general medical-use strain information). ***Important Note: It is customary for the BOP to approve labels in NYS. We stand prepared to implement standards as promulgated.***

An internal chain-of-custody process will be in place. All products removed from the Restricted access Area will be logged into "States Selected Software" inventory system and digitally signed by the Pharmacist or Pharmacist Technician who conducted the transaction.

3.5 Product Offerings

The Company will offer the highest quality and widest variety of cannabis-based medicines available in order to meet our customer's medical needs and preferences. We will also provide high quality, functional, and safe method-of-delivery products and ancillary products for storing and cleaning them. The Company will only be able to offer patients those medical-cannabis products produced by the manufacturing site. We will continuously update the Company's comprehensive medical-cannabis database as new products become available from the cultivation center, as approved by the State. The database will contain tested values of each product batch (THC, THCa, THCv, CBD, CBN, CBC, THC/CBD ratio and any other test values available), which will effectively address the symptoms of NYS approved conditions.

Patients often want to choose their products on the basis of the delivery method. Patient options for delivery include: vaporizing, sublingual spray or strips, oral mucosal sprays, gelcaps, and oral syringes. It will be the physician's choice in the beginning of therapy, however patients once educated will be interested in alternative delivery options

With all the available options, patients are bound to be interested in their options. To help patients make their choices among the many products and delivery systems, our pharmacists will assist patients in understanding our educational material, which contains a wealth of information about products and strains and their various methods

of delivery, conditions for which they are used, dosage, side-effects, and other information. Patients will then be able to make educated choices among Sativa, Indica, and Hybrid varieties of various strengths and ratios of the active components.

3.6 Recordkeeping

The State Selected Software will be the primary holding site for relevant information. However certain hardcopy documents may be stored. Kinex Supportive is committed to storing that information at a length of time that is dictated by the type of document. For paper records, the following process will be implemented.

At the end of each day, hard copies of all patient documents successfully scanned and entered into the system will be shredded. For any paper records needed in hard copy, any patient files will be created with last name, first name in alphabetical order and be stored in fire safe, locked file cabinets in a secured metal caged area within the Company's restricted access area.

The Company's procedures to ensure all records are properly updated as new information becomes available include direct inquiry and interview with each patient at each visit or phone consultations to determine any change in their medical status or response to treatment. Entry of the information will be prompted into the "State Selected Software" system. As new products become available, that information will be entered into the "State Selected Software" system.

To ensure accurate records are created, properly maintained, and updated regularly, the Company will extensively train its staff on all technology and systems appropriate to their level of security clearance. This includes the "State Selected Software" patient and inventory dispensing and POS system, the security systems, internal financial reporting, and audit processes and systems. The Company will ensure that all employees' educational training includes The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Hitech provisions. In addition to HIPAA training, all Company employees will receive compliance training that will include, but is not limited to, the mission and vision of the Company to provide the highest levels of attention to professionalism and integrity with a focus on the patient and caregiver, public safety, Federal and State laws and regulations regarding medical cannabis, patient rights to privacy and confidentiality and confidentiality of the Company's information and operations.

3.7 Diversion identification

Overseen by the Company's Pharmacist in Charge, our staff will use the State Selected System to track the patient's purchasing history to minimize the risk of diversion by patients. To prevent diversion, the Company will follow state guidelines exactly.

Notwithstanding these safeguards, if the Company discovers that a patient has diverted medical cannabis, that patient will be immediately barred from purchasing medical cannabis from our dispensary, and reported to authorities. The Company maintains a

zero tolerance policy regarding employee drug or cash diversion. In the event Company discovers that one of its dispensary employees has diverted medical cannabis or cash, Company will immediately terminate the employee. Company will notify local law enforcement authorities and the DOH immediately in both cases.

3.8 Audit Considerations

The Company will, at all times, comply with all audit requirements. In addition, the Company will have our regulatory compliance officer with extensive knowledge of regulatory matters. Our compliance officer will ensure that our methods of record-keeping meet the highest standards.

We will maintain most records (patient, inventory, audit, inspection, business plans and processes, employee records, management reports, and State Licenses and Registrations, etc.) electronically in the “State Selected Software” system and make them immediately available for inspection and/or copying by the Division upon request. Those records that require a paper back-up will be stored on-site or at a sister site depending on the volume of paper generated and the available space at the dispensary. All paper records will be made available for audit upon request within a reasonable amount of time. Company will provide private office space for the DOH to use for this purpose.

In particular, the Pharmacist in Charge will conduct and document an audit of the dispensary's inventory according to Generally Accepted Accounting Principles (GAAP) once every 5 days. In our files, the Company will also maintain evidence of all training provided for every agent in the event that such agents might be subject to inspection and audit by the Division. We will also maintain copies of the policies and procedures on our premises and provide copies to the DOH whenever requested. These policies will be reviewed throughout each fiscal year and modified to comply with all rules and regulations as they are promulgated. The Company will also respond to all notices required by the DOH, e.g., reporting a change in management or a pharmacist in charge.

The Company understands that it may/will be subject to random and unannounced dispensary inspections and cannabis testing by the DOH and we will fully cooperate with any inspections or testing.

3.9 Record Inspection

The Company's Pharmacists are accustomed to State and Federal inspections. Because of this valuable "inspection" familiarity, the Pharmacist knows how to store and maintain confidential files and records to provide easy, efficient and immediate access for State inspectors. The “State Selected Software” system will keep all of the Company's procedures, policies, registration information, patient and inventory, and compliance and audit records digitally on the HIPAA compliant server and organized by folder for easy accessibility to State inspectors. The “State Selected Software” system will also provide task creation and milestone tracking to monitor every aspect of the dispensary facility's operations. Hard copy documents not digitalized will be organized by folder and filed in a locked file cabinet stored in the restricted access area. Hard copy data will be readily

accessible to State inspectors.

3.10 Inventory Controls:

Inventory Controls are a key part of any pharmacy operation. Kinex Supportive Pharmacists will follow the corporate inventory schedule, and we will utilize corporate accounting staff to validate the inventory counts at least monthly. The inventory system will be balanced against at least, patient purchasing histories, patient medical cannabis card records including activation and expiration dates, and prior inventory reports. The application and oversight of the Company's inventory control system will be the responsibility of the Chief Operations Officer, and Chief Security and Compliance Officers. The Company's inventory control system through "State Selected Software" manages the complete chain of custody timeline of the Company's medical cannabis from its initial purchase from a cultivation center to point of sale to the registered patient or caregiver. The Company's inventory control system uses state-of-the-art technology to ensure that it is compliant with NYS state law and regulations throughout the dispensary inventory tracking and sales process. The "State Selected Software" inventory system creates a real-time inventory report which is web-accessible to the Department at all times.

The pharmacist in charge will be responsible for inventory and entering their findings directly into a hand-held barcode scanners supported by the software. The "State Selected Software" system will provide the Company with an end-of-day cannabis purchase history by product. The system will reconcile daily purchases to an end-of-day cannabis inventory report. This end-of-day inventory report will represent all product removed from the restricted access area. Daily, weekly, monthly, and annual reconciliation will compare inventory in the restricted access area to patient purchase records. In addition, physical inventories of product will be conducted on at least every five days by the Pharmacist in Charge, with monthly counts by the Director of Security. The "State Selected Software" system will log all products sold to patients. System records will retain all details of product transactions product, amount, date and time of sale, seller, and price.

In the event of a discrepancy between cultivation center received product(s), disposal product(s), and total cannabis dispensed/sold to patients, the Company shall immediately perform an internal audit to determine the reason for the discrepancy. Immediate access to video surveillance camera feedback to assist with an issue will be used if necessary. If the pharmacist determines that there is an error or inaccuracy in its inventories, then it will investigate the cause and immediately put into place corrective operational measures to avoid such error or inaccuracy in the future. If the discrepancy cannot be resolved (sales, vs. on-hand, vs. received inventory product(s)), the DOH and local police will be notified within forty eight hours of the discovery of the discrepancy. In the event that the Company determines or suspects that criminal activity may have been involved, the Company shall submit a report to the DOH and the NYS State Police identifying the circumstances surrounding the discrepancy.

3.11 Ongoing Training Requirements

Each Company employee will receive compliance training upon hire and on at least an annual basis thereafter. The compliance training ensures the employee understands the following: (1) the Company's mission and vision-to provide the highest quality of medical cannabis in accordance with the highest levels of attention to professionalism and integrity, with a focus on the patient, caregiver and public safety, (2) Federal and State laws regarding medical cannabis, (3) patient rights to privacy and confidentiality, (3) confidentiality of the Company's information and operations, (4) the Company's policies and procedures regarding security and (5) the Company's policy and procedure on emergency preparedness. All employees' educational training will include detailed information on, and how to comply with, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Hitch provisions.

3.12 Returns

The Pharmacist in Charge will be responsible for determining when products need to be destroyed, or quarantined for recall issues. All products deemed to be destroyed or stored for further study must be returned to the manufacturing center to be managed as per the recall plan. Company will not dispose of any product at its facility. Through the "State Selected Software" system, company will maintain a log that will include: product that was returned to the cultivation center for destruction, description of the product, the circumstances, and other pertinent details. The pharmacist in charge and the security staff transporting products will sign the destruction manifest. The security driver will sign a receipt. Dispensary product to be returned to the manufacturing center will be placed in the vehicle safe and well-marked bag/box sealed with a thick plastic chain-of-custody security tie. Company will dispose of unusable product bi-weekly and provide appropriate notice to the DOH. Company will also keep a log that describes the product and the reason for its disposal, along with any other pertinent information.

Company will use the inventory-adjustments module of the "State Selected Software" system to record manual inventory adjustments through a detailed notes section. The reason for disposal and disposal process can be recorded and archived up to a 16-digit barcode associated with the disposed cannabis. We will maintain and save hard-copy product destruction manifests and destruction digital records from "State Selected Software" will be for 7 years.

Section 4: Devices

MANUFACTURING AND PRODUCTION

Redacted pursuant to N.Y. Public Officers Law, Art.6

Section 5: Security and Control

Redacted pursuant to N.Y. Public Officers Law, Art.6

Section 6: Standard Operating Procedures

Manufacturing and Cultivation

Starting materials that are used to produce a botanical drug substance will be evaluated for quality during the receiving process to determine if they meet the basic criteria to be utilized in the production process. The use of appropriate starting materials and the ability to control the source depend on appropriate specifications (tests, analytical procedures, and acceptance criteria). In addition to establishing specifications, the Quality Assurance officer will achieve adequate quality control of starting materials by applying the principles outlined in FDA's botanical guidance and by following good agricultural practices.

Upon receipt of the starting materials at a processing facility, the Quality Assurance Officer's responsibility is to determine the suitability of these raw materials before use. This will be accomplished by examining and/or testing to ensure that the acceptance criteria are met and by documenting the quality control for the processing of the starting materials.

6.1.1 Manufacturing Component Control Requirements

(a)) Manufacturing operations will have written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, review, and approval or rejection of components.

(b) Each container or grouping of containers for components will be identified with a distinctive code (i.e. lot number) for each lot in each shipment received, which allows the lot to be traced backward to the supplier, the date received, and the name

of the component; and forward to the marijuana-derived product batches manufactured and distributed using the lot. This code will be used in recording the disposition of each lot.

(c) Specifications for each component will be established as follows, to the extent they are necessary to ensure that manufactured batches of marijuana-derived product meet specifications.

(1) An identity specification for the component will be established;

(2) Specifications for the strength and composition of the component will be established as necessary to ensure the strength and composition of marijuana-derived products manufactured with the component;

(3) Specifications for the purity of the component will be established as necessary to ensure the purity of marijuana-derived products manufactured with the component, including limits on those types of contamination that may adulterate or may lead to adulteration of marijuana-derived products manufactured with the component, such as filth, insect infestation, microbiological contamination, or other contaminants.

(d) Components will be received and stored pending approval as follows:

(1) Upon receipt in the receiving area and before acceptance, each container or grouping of containers will be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination, to determine whether the container condition may have resulted in contamination or deterioration of the components.

(2) The supplier's documentation for each shipment will be examined to ensure the components are consistent with what was ordered.

(3) Components will be stored under quarantine until they have been sampled, reviewed, and approved or rejected by the Quality Control Officer.

(e) Components will be approved or rejected as follows:

(1) Each lot of components will be withheld from use until the lot has been sampled, reviewed, and released for use by the Quality Control Officer.

(2) Compliance of the lot with established specifications will be ensured either through review of the supplier's certificate of analysis or other documentation, or through appropriate tests and/or examinations. Any tests and examinations performed will be conducted using appropriate scientifically valid methods.

(3) Any lot of a component that meets its specifications may be approved and released for use for use by the Quality Control Officer.

(4) Any lot of a component that does not meet its specifications will be rejected by the Quality Control Officer, unless The Quality Control Officer approve a treatment, process adjustment, reprocessing, or other deviation that will render the component or packaging component

suitable for use, and will ensure the finished marijuana product batches manufactured with the affected lot will meet all specifications for identity, purity, strength, and composition and will not be otherwise contaminated or adulterated. Any such treatment, process adjustment, reprocessing, or other deviation will be documented, justified, and approved by the Quality Control Officer

(f) All components will be received in the receiving area and inspected prior to being authorized to be taken to the proper storage area.

(g) "State Selected Software" incorporates extensive financial tracking within purchases and cost can be tracked for everything ranging from lighting, nutrients, packaging, etc. Purchases of any kind can be tracked as bills, which include the vendor information, time and date of purchase, as well as the financial details of the transaction. This information can be exported to QuickBooks or included in financial reports. Any financial transaction can be populated and tracked as a one-time or automatically recurring bill. These expenses can be exported to QuickBooks. "State Selected Software" allows for supporting documents to be scanned and attached to transactions, ensuring that financial records are complete.

6.1.2 Components to be received:

Once a component is approved by the Quality Control Officer it will be taken to its designated storage area.

a) Receiving Area Racks and Rooms

1) Rockwool
2) Grodan Slabs
3) Seeds
4) Seed Sowing Pipette
5) Cultivation Utensils
6) Canopy Netting and Poles
7) RFID Tags
8) White display trays
9) Reverse Osmosis Filters
10) Replacement HPS, MH, and LED Lights
11) Protective Gloves
12) Protective Uniform jumpsuits.
13) Composting soil
14) Pesticides (Pesticide Room)
15) Fertilizer (Fertilizer Room)
16) DFE Cleaning Chemicals (Janitorial Closet)

b. Extraction Laboratory

1) CO_2 tanks
2) Extraction Utensils
3) Extraction Chemicals
    a. Ethanol
    b. Glycol Alcohol
4) Testing Utensils
    a. Petri dishes
    b. Pipettes
    c. Filter Paper
    d. X-Ray Cups
    e. 2 ml Microfuge tubes

5) Chemicals
    a. Methanol
    b. 2-Propenol
    c. Acetonitrile
    d. Glacial Acidic Acid
    e. Hydrochloric Acid

c. **Trimming Area**

1) 2 Gallon glass Jars
2) Wax Paper
3) Garbling Utensils

d. Packaging Components

1) Pharmaceutical Bottles
2) Lids
3) Gauze
4) Labels/ Shrink Sleeve
5) Tamper Evident Bands

6.2 RFID Tag Tracking & Printing

Inventory control is one of the most critical components in running a successful and fully-compliant pharmaceutical business. Inventory management threads through the entire operation and touches all the areas that are important to the operation and to those that regulate it. Without good inventory management, there is risk of security breaches, diversion, loss of quality, theft, and lack of accountability by the staff. The Company's inventory control plan is designed to ensure safekeeping of marijuana throughout the lifecycle of the product.

At the foundation of the Company's inventory control plan is "State Selected Software" a robust enterprise software platform designed specifically for the highly-regulated marijuana industry. This technology enables The Company's to track every action performed on every plant from its creation (whether from seed or clone) to finished marijuana product, every movement of the inventory, and every wholesale and retail sale, capturing batch and lot numbers throughout and ensuring the security and traceability of all inventory at all times. This all-encompassing process is commonly referred to as "seed to sale" tracking.

6.2.1 Manufacturing & Dispensing Functionality

"State Selected Software" offers seeds to sale features to enable the company to track and record all necessary manufacturing and dispensing operations and retain 100% compliance with Department guidelines.

6.2.2 Tracking Plant

Batches

a) Upon creation, groups of plants propagated together and of the same strain will be identified as a batch. A batch is defined as a combination of plants of the same cultivar(strain) that were planted at the same time, under identical conditions, and harvested at the same time. While on average 1,200 seeds/clones will be propagated approximately every week in a Green Pod propagation chamber, to assure homogenization and accurate batch lab testing, a batch will consist of no more than 250 plants or approximately 25 pounds. This is based upon the approximate flower yield from 250 square foot greenhouse zone area (average yield estimated at 50 grams of flower per plant).

b) Batches of plants are kept together in the same physical location and are treated identically throughout their lifecycle, including their stage in cultivation, applied nutrients and additives, and labor processes. This data is captured in "State Selected Software" module and tracked throughout the entire growth process. Details such as genetic line, plant health, growth rate, cost of equipment used in each growth phase, and cost of nutrients and additives applied throughout all stages of growth are also tracked. Most importantly it allows a physical inventory to be performed of all plants and medical marijuana containers on a weekly basis.

c) Everything that happens to the plant during its lifetime is recorded and tracked by its RFID tag for a period of 5 years, including:

1. genetic history and mother plant (the plant from which the cuttings are taken)
2. cultivar (strain)
3. schedule and stage (including creation date and forecasted time until another

4. change occurs in the lifecycle)
5. watering and light cycles
6. nutrient application
7. staff identification (at each step)
8. physical location of the plant at all times

6.2.3 Plant Inventories

a) An inventory of all plants is performed by the Cultivation Manager on a daily or weekly basis.

b) "State Selected Software" automatically assigns a globally unique and non-repeatable 16-digit barcode number to every plant. The system auto-generates a globally unique and non-repeatable 16-digit barcode number at every stage where marijuana must be separately identifiable from the original plant due to processing and packaging. These serial numbers, once generated are assigned, cannot be changed

c) Batches of plants are inventoried by scanning barcodes of each plant, at which point "State Selected Software" has the ability to compare current physical plant inventory versus last recorded (expected) plant inventory. In the propagation phase, this takes into account any plants that have been added to inventory, which in this phase would be by creation from seedling or clone, any plants that were removed from inventory or moved to another phase of its lifecycle, and any plants that have been destroyed. Any discrepancy in physical plant inventory is traced to the source of the discrepancy, documented, and reported to the Quality Control Officer and as regulations require. After further investigation, any appropriate corrective measures are taken.

6.2.4 Tracking Actions of Plants

a) The Cultivation Agent-In-Charge oversees the propagation process and monitors the cuttings daily. Well-documented propagation procedures ensure that cuttings taken, as well as actions performed during the propagation phase, are tracked. The staff person performing any activity is recorded in "State Selected Software". The entire cultivation facility is monitored through video surveillance.

b) Actions performed on plants are tracked by scanning individual plants or by scanning entire batches of plants and recording the action taken. This includes watering, feeding, plant movement from one physical location to another, plant destruction due to plant sickness or pest infestation, plant progression through different stages of cultivation, changes in light cycles, changes in nutrient application, and so on.

6.2.5 Security

a) "State Selected Software" is available as a cloud-based; meaning the program is run, and data is stored, on remote, highly-secure servers. This offers an added layer of security and redundancy should there be a failure on a hardware device or an interruption in power. Cellular connections ensure that communication is intact if the internet connection is lost.

b) "State Selected Software" is a secured program that is password protected and also can be set for Biometric Fingerprint scanning to ensure only authorized personnel will be able to access secure documentation within the system. All the information is stored on a local server that is firewall protected from any outside presents.

c) Users access the software with unique identification which is linked to specific roles and permissions within the software. This ensures accountability for, and oversight of, the business activities which can be monitored by upper management, owners, and regulators at any time, from anywhere.

6.2.6 Diversion Prevention Functionality

a) "State Selected Software" has a biometric chain of custody module that logs every action in real time and the user who performed that action. "State Selected Software" has the ability to integrate with scales to deter employee theft and human error. Every piece of data is captured with a time and date stamp by user, ensuring a clearly documented chain of custody at all times. Because every action is time stamped it can be cross referenced with security cameras. All of these functions prevent diversion, abuse, and illegal or unauthorized conduct relating to medical marijuana.

6.2.7 Recall Functionality

a) Each receipt that "State Selected Software" produces at the conclusion of a sale has a unique barcode that can easily be scanned to view the details of that sale. After a refund the items are returned to the inventory count. You have the ability to separate your inventory in the system in order to quarantine the returned items. "State Selected Software's" reporting abilities allow you to track and monitor these actions. It also has the ability to contact patients via email or SMS text message that have purchased a particular product in the past.

b) "State Selected Software" can adjust inventory and always require a reason for removal when utilizing the inventory adjustment feature, also it has an auditing feature that can be used to track loss of product due to diversion or theft. Although the inventory can be adjusted or voided, at no time is any data ever fully deleted as "State Selected Software" maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of

the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

6.2.8 Reporting Functionality

a) The reporting engine within the software suite is robust and can bring key business process information to light to the owners/managers of the business including:

1. inventory-level planning
2. cost tracking
3. in-depth sales analysis
4. vendor purchase orders
5. inventory analysis
6. patient/customer order history
7. staff productivity
8. compliance reporting
9. employee identity and badge number
10. vehicle vin number
11. time stamped batch/lot number
12. total quantity being transported

b) "State Selected Software's complete tracking of every plant and inventory item within a facility and the ability to notate the exact location of any individual item will streamline any inspections, allowing you to do what is important like running your operation to maximum potential.

c) With "State Selected Software's robust real-time reporting infrastructure any required records can be retrieved at any time. The system enables the business to collect, store, and retrieve all data and activity. Though system actions can be adjusted or voided, at no time is any data ever fully deleted as "State Selected Software" maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary during an inspection or at a Department's request.

d) Within "State Selected Software" there are numerous sales and inventory reports that can identify that exact time a sale was made, the items dispensed and the employee that made the transaction. Additionally "State Selected Software" requires that each patient be added to the system with all relevant information before a sale can be made. This information includes the quantity that that patient is allowed to purchase. Patient sales amounts can be automatically set within the system to prevent any transaction outside of permitted limits. The time sales occur can be set in the system to prevent sales outside of hours of operation.

6.2.9 Record Retention Functionality

a) "State Selected Software" enables the business to collect, store, and retrieve all data and activity. All inventory records, patient records, recall reports, sales/transaction records, product disposal records, and all scanned documents can be accessed at any time (real time), either in-system or through the report creation tool. Though system actions can be adjusted or voided, at no time is any data ever fully deleted as "State Selected Software" maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

b) Reports are retained beyond the five year requirement and can be accessed indefinitely. In addition to storing information, the system also has the ability to create custom labels for cultivation, manufacturing and testing results.

6.2.10 Product Label Creation Functionality

a) "State Selected Software's label creation tool enables the company to create custom container-client labels with any fields necessary to comply with applicable law. The easily readable patient specific dispensing label approved by the department will easily affix to the approved medical marijuana product package. The company can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale.

b) The "State Selected Software" label creation tool allows generates transaction specific information including;

(1) the name and registry identification number of the certified patient and designated caregiver, if any;
(2) the certifying practitioner's name;
(3) the dispensing facility name, address and phone number;
(4) the dosing and administration instructions;
(5) the quantity and date dispensed; and

(6) any recommendation or limitation by the practitioner as to the use of medical marijuana

6.2.11 Sampling & Lab Testing Functionality

a) Within "State Selected Software" there are a number of functions designed specifically for use with laboratory testing. This includes but is not limited to the following:

(1) Laboratory facility detail information options to notate lab credentials
(2) Log and directly associate lab results with a specific lot or batch of

product.
(3) Inventory adjustment logging for testing sample removals
(4) Ability to separate products pending testing from available inventory
(5) Direct porting of lab results to product labels

6.2.12 Waste Disposal and Destruction Functionality

a) Marijuana plants and products that do not meet standards for health, quality, and viability are destroyed. This includes any plant that may be diseased, damaged, or otherwise substandard. Only a limited number of authorized staff will be permitted to destroy plants. These staff members record the destroyed plant weight and the reason for destruction in "State Selected Software". All compostable material is composted on-site to reduce the amount of waste for disposal. All plant waste is mixed, fifty-percent (50%) by volume, with an approved inert material, and disposed of by an approved and licensed waste management company.

b) "State Selected Software" can adjust inventory and always requires a reason for removal when utilizing the inventory adjustment feature. Product in need of quarantine can be separated from bulk and placed in the designated area. The system has the ability to separate and quarantine products that do not meet the minimum standards for Safety and Brand consistency. If a product must be destroyed the system will document the destruction in accordance with the registered organization's approved operating plan.

c) Inventory destruction can be initiated through the system requiring documentation of destruction purpose and/or approved method as well as the employee performing the action. Although the inventory can be adjusted or voided, at no time is any data ever fully deleted as "State Selected Software" maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

6.2.13 Transport Functionality

a) Upon preparing an order for transport the company will create a standardized shipping manifest. This action must be completed before the system will allow documented transportation. The report will contain, but not limited to, the following information.

1) employee identity and badge number
2) vehicle vin number
3) time stamped batch/lot number
4) total quantity being transported.

b) A shipping manifest will be generated by the system that can be electronically transferred to the department and the dispensing organization. This information will be retained in the system beyond the 5 year requirement and will be available indefinitely for the department to request.

c) To track that the company's authorized employee travels directly from the manufacturing facility to the dispensing facility without unnecessary stores, the "State Selected Software" system will generate point-to-point directions and estimated travel times using the predetermined addresses of the manufacturing facility and the dispensing organization. GPS locators and 3g cameras embedded in the transport vehicle are discussed in greater detail in the transportation section.

6.2.14 Dispensary Functionality

a) To ensure the Dispensing facility never operates without a licensed New York Pharmacist on Duty, the system has the ability to implement a "pharmacist on duty" parameter. Specified hours of operation can be put in place to prevent sales from occurring outside of these hours.

b) Prior to any transaction taking place a certified patient or designated caregiver must be verified and checked in to the system in order to assure a medical marihuana product is not sold to anyone other than a certified patient or designated caregiver.

c) To prevent a certified patient from exceeding its 30 day supply limit or making a purchase before said patient has exhausted all but a seven day supply provided pursuant to any previously dispensed medical marihuana product by any registered organization; the software assigns each registered patient a revolving 30 day limitation. The system tracks all items dispensed for a patient and automatically deducts from said limit. If a patient attempts to purchase any products beyond their limitations the system will prevent the sale from occurring.

d) "State Selected Software" maintains a patient history log that can be accessed either directly from the patient profile or from the backend reporting. This enables the company to track patient specific usage of marihuana products, i.e brand, administration form, and dosage, and dates dispensed and any return of product which can be shared with a patient's designated caregiver, if applicable, or the patient's practitioner upon request;

e) To ensure the company's dispensing facility shall ensure that each patient receives approved medical marihuana product from no more than two distinct lots for any 30-day supply dispensed, each plant grown, as well as products created can be assigned to a specific patient within the system. The 16 digit identifier for any given product can be selected upon fulfillment of an order. This allows for compliance with the two distinct lot rule.

f) “State Selected Software”’s sales ticket reporting feature allows a record of all approved medical marihuana products that have been dispensed to exported electronically to the department, not later than 24 hours after the marihuana was dispensed to the certified patient or designated caregiver.

g) The information filed with the department for each approved medical marihuana product dispensed will include but not be limited to:

(1) a serial number that will be generated by the dispensing facility for each approved medical marihuana product dispensed to the certified patient or designated caregiver;

(2) an identification number which shall be populated by a number provided by the department, to identify the registered organization’s dispensing facility;

(3) the patient name, date of birth and sex;

(4) the patient address, including street, city, state, zip code;

(5) the patient’s registry identification card number;

(6) if applicable, designated caregiver’s name and registry identification card number;

(7) the date the approved medical marihuana product was filled by the dispensing facility;

(8) the metric quantity for the approved medical marihuana product;

(9) the medical marihuana product drug code number, which shall be populated by a number provided by the department, to represent the approved medical marihuana brand that was dispensed to the certified patient or designated caregiver, as applicable;

(10) the number of days supply dispensed;

(11) the registered practitioner’s Drug Enforcement Administration number;

(12) the date the written certification was issued by the registered practitioner;

(13) the payment method.

h) When applicable and requested by the Department, the company shall utilize the software that captures all patient product sale information as well as all necessary static fields, to file a zero report with the department no later than 14 days following the

most recent previously reported dispensing of an approved medical marihuana product or the submission of a prior zero report.

i) To perform the Department mandated "cost analysis" to determine if the proposed costs represent what the price per unit for approved medical marihuana products should be under reasonable economy and efficiency, the software cost of inventory can be entered into the system for specified lots of product. Once sales have commenced the system will be able to provide profit/loss margins for products sold. These records shall be retained indefinitely and shall be available for examination by the department to adequately evaluate the proposed price.

j) The department may perform audits, which may include site visits. The registered organization shall provide reasonable access to the department of its facilities, books and records. □"State Selected Software" retains all actions performed in the system indefinitely. All records that are captured by the system within a given registered organization are accessible upon request to perform department audits of the company's facility, books, and records.

6.2.1 Hardware

The Hardware platform is composed of a Control Tier and a Device Tier. The requirements and configuration of these tiers are described below.

The Control Tier environment may exists as any of the following:

- A commercial servers running Linux or Windows (spec below)
- A laptop (for smaller business use cases)
- A VM slice provided by The Company

6.2.2 Commercial Server Requirements (Control Tier)

Item	Definition	Comments
CPU Processor	2x Quad Core, 10MB Cache, @2.4 Ghz or higher	2x- Intel® Xeon® Processor E52609 (Quad Core - 2.4 GHz, 10MB Cache)
Memory	16 GB or higher	16GB PC3-10600 ECC (DDR3-1333) Registered DIMMs

Item	Definition	Comments
NIC	Gigabit Ethernet	
Hard Drive	300 GB usable, 15K rpm, preferably in hardware raid configuration with 1GB Cache (min) controller	4x-146GB - 2.5" - SAS-2 - 15000 rpm in RAID Configuration (~292 GB Usable)
Power Supply	Dual Hot-plug	
OS Support	RHEL V5.5 OS or Windows 2008	

6.3 Wireless Handheld Requirements

Item	Definition	Comments
OS	Windows CE 5.x, Windows Mobile 5.x or 6.x	
Scanner Engine	2D Imager (minimum)	
Keypad	53 Key (preferable for data entry to support exception processing)	
Touch Screen	Recommended	
Memory	Required 25 MB Flash free space and 64 MB RAM (min)	

6.3.1 Hardware Devices

6.3.2 Serialization

The “State Selected Software” system supports printing and verifying serialized GTIN labels (SGTIN) for application to previously non-serialized saleable goods.

a) The “State Selected Software” system is based on the following Serial Number assumptions:

   1. Serial Number ranges may be electronically downloaded from the Serial Number Management System (SMS)
   2. “State Selected Software” automatically assigns a globally unique and non-repeatable 16-digit barcode number for every plant
   3. The system auto-generates a globally unique and non-repeatable 16 digit barcode number at every stage where dried marijuana must be separately identifiable from the original plant due to processing and packaging.
   4. These serial numbers, once generated are assigned, cannot be changed.
   5. Serial number ranges are provided in advance and manually input into the “State Selected Software” system for the use in the printing process

b) “State Selected Software” supports separate User Permissions for the Print and Verify functions. This feature enables The Company to grant access to only authorized personnel for specific production areas.

6.3.3 Print function.

a) The “State Selected Software” tags printed conform to RFID Standards

b) It allows the user to initiate the print by scanning or manually entering the 1D product barcode label utilizing a handheld device

c) It shows the GTIN in read only mode if there is only one GTIN associated with the product in the product master

d) It provides a drop down of the GTIN for selection based on the Product Master if there is more than one GTIN associated with the product

e) It allows users to scan a 1D linear barcode label for Lot and Expiry or manually enter the Lot and Expiry

f) It requires users to manually enter a print quantity

g) It performs the following tasks when a user selects 'Print'

    1. Allows the user to change the printer selection prior to initiating the print job
    2. Confirms that the selected printer is in a 'Ready' state and sends the print job to the printer.

h) It prompts the user that the print job has been submitted and allows them to continue to print additional tags for the lot or complete printing for the lot

i) It communicates EPCIS Object XML events to the SMS with the following data elements once a print job has successfully been submitted to the printer. All S/Ns associated with the print job are communicated

    1. Serial Number(s)
    2. GTIN
    3. Lot
    4. Expiry

6.3.4 Correct Labeling Assurance

Listed below are the key business processes and solution design assumptions that pertain to the **Verify function** which ensures the labels are applied to the correct product.

a) "State Selected Software" allows the user to scan 2D serialized bar code labels created in the "State Selected Software" system once the Product Details are established for the verification process

b) It verifies the product, lot and expiry from the printed tag against the Product Details input by the user

c) It only commissions tags that have been verified

d) It communicates EPCIS Object XML events to CSC for S/N's upon user completion of the Verify process containing the following information

    1. Serial Number(s)

2. GTIN
3. Lot
4. Expiry

6.3.5 Tag Creation Station

"State Selected Software" supports the printing and commissioning of RFID tags.

a) Tag Creation stations will be located across the facility in the following locations
    1. Propagation
    2. Outside of the Vegetative Greenhouse prior to the Flowering zones
    3. Trimming/Manicuring Room
    4. Lab Extraction
    5. Curing vault
    6. Packaging
    7. Disposal area
b) "State Selected Software" provides the ability to select the desired printer from a list of available/configured printers.
c) It supports printing tags based on both a serial number range and a randomized list of serial numbers
d) It supports the input of the following data attributes to initiate the tag creation process
    1. Product
    2. Lot
    3. Expiry
    4. GTIN or Container Hierarchy
e) It supports printing tags to a printer including all information based on the print template associated with the GTIN(s) and/or SSCC
f) It supports printing tags to both a printer and a PDF file for a given tag creation job
g) It provides the capability to print tags for a specific GTIN (no aggregation)
h) It provides the capability to print tags for a specific container hierarchy, including the capability to:
    1. select and deselect what levels to print in a hierarchy

2. print tags in Hierarchy sequence (i.e. Plant Batch, Group A, all plants in Tray A, Tray B, all plants in Tray B, etc.)
3. aggregate printed serial numbers based on the container hierarchy selected and transmit serial number aggregation information to the external SMS

i) It provides the option to configure receiving of parent serialized containers in Audit Mode

1. The solution allows a configurable percentage of child containers(individual plants/products) required to be scanned to be specified for parent containers(batches)
2. The solution calculates an Audit Count based on the contents of the container and the configurable audit percentage
3. The solution tracks the receipt scans against the Audit Count
4. The solution considers the parent container contents fully received when the required Audit Count of child containers is successfully completed in Audit Mode
5. The solution reverts to 'full scan' mode if an error (e.g. an unexpected serialized child container is encountered based on the parent container serial number hierarchy downloaded from the SMS) is found on any of the child container scans in Audit Mode

j) It provides the capability to suspend and resume receipts

6.4 Mother Room:

All marijuana plants will begin their life cycle in the Mother Room. After the first crop of plants developed from seeds completes the vegetative cycle, the 500 square foot growth chamber designated for mother plans can begin to be populated. Mother plants require constant environmental conditions to sustain a healthy, vegetative state in order to provide healthy cuttings for clones over periods of months or years. Metal halide lights emitting 400-500 umols will maintain the plants in the desired vegetative state. The climate will be maintained at a constant temperature between 70-78 F and relative humidity between 40-50%. **Exhibit E** shows a sample image of a controlled environment growth chamber that can be utilized as a mother room.

Exhibit E: Climate Controlled Mother Room

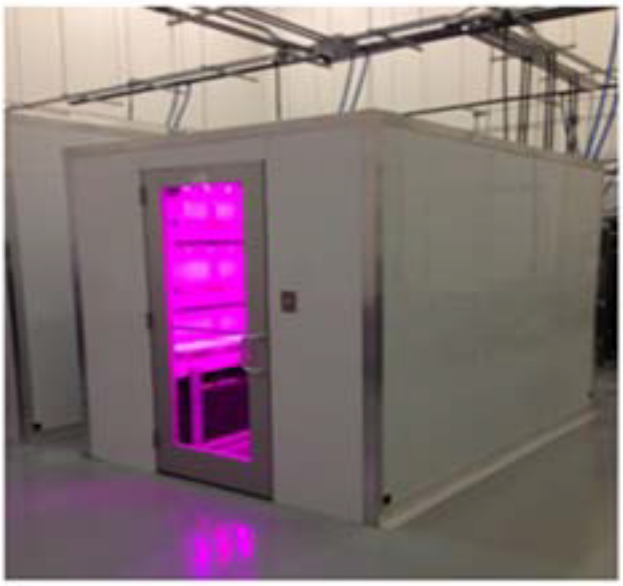
6.5 Seed sowing and transplantation of seedlings:

Upon completion of the cultivation area, cultivation will commence from seeds initially. Seeds and eventually all clones will be propagated in Green Pods **(Exhibit F)**. A Green Pod is a self-contained, 4 tiered, highly environmentally controlled growth chambers that will provide the optimal growth environment for up to 1,200 juvenile plants at a time. Seeds will be sown in sterile Rockwool plugs. Seeds will be sown uniformly approximately 1 cm deep and at least 1cm apart by the Plant Breeder utilizing a laboratory grade seed sowing pipette **(Exhibit G)**. The Rockwool will be of sufficient volume (> 2 in^3) to enable natural downward and lateral root development prior to replanting. The Rockwool will be maintained at an even moisture content of approximately 70% until roots have developed. This is the only portion of our facility where the plants are not maintained by the centralized irrigation system. The propagation section will utilize the skill of a grower in knowing how to encourage root development. Rooting is typically the most difficult action for beginner growers and that is why we choose to employ growers with experience and education for these skilled areas. The temperature will be maintained at 70-80F with a relative humidity between 60-99%.

LED lighting will provide 300 umols of light 18 hours per day. Misting of pure water may be necessary until seedling emergence to reduce surface drying of the Rockwool.

Ideally seedlings will be ready for transplanting approximately 14 days after sowing. At that time hypocotyls are usually around 6 in tall and multiple pairs of true leaves well formed. A sterile Rockwool block will be prepared according to manufacturer's instructions using ph'ed water and the plug will be inserted into the predrilled hole, this ease of transplant will prevent physical damage to the root system as well as prevent transplant shock and further stress to plant. The growth medium will be sufficiently watered and fertilized to maintain moisture around the seedling and encourage growth rate increases. At this point a unique, water-proof RFID tag will be printed out and placed around the young planting to track its progress as a as a part of a batch number until it reaches the height of 18 inches in vegetation when it will be assigned a unique numerical plant identification number in conjunction with its plant batch number. This will enable the tracking of the plant from seedling to store.

Exhibit F: Propagation Green-Pod Chamber



Green-Pod Specifications & Features

- 7' wide x 12' long x 8' tall
- Temperature 65F-90F +/- 5F
- Humidity 30%-60% +/- 5%
- 24 Hour Photoperiod Control
- Independent Irrigation Control
- Drip/Sub/NFT Irrigation Options
- Multi-Level 6 Tier Racking System
- Remote Sensing
- Single 50AMP connection
- Fob Controlled Security Access
- Flexible Configurations

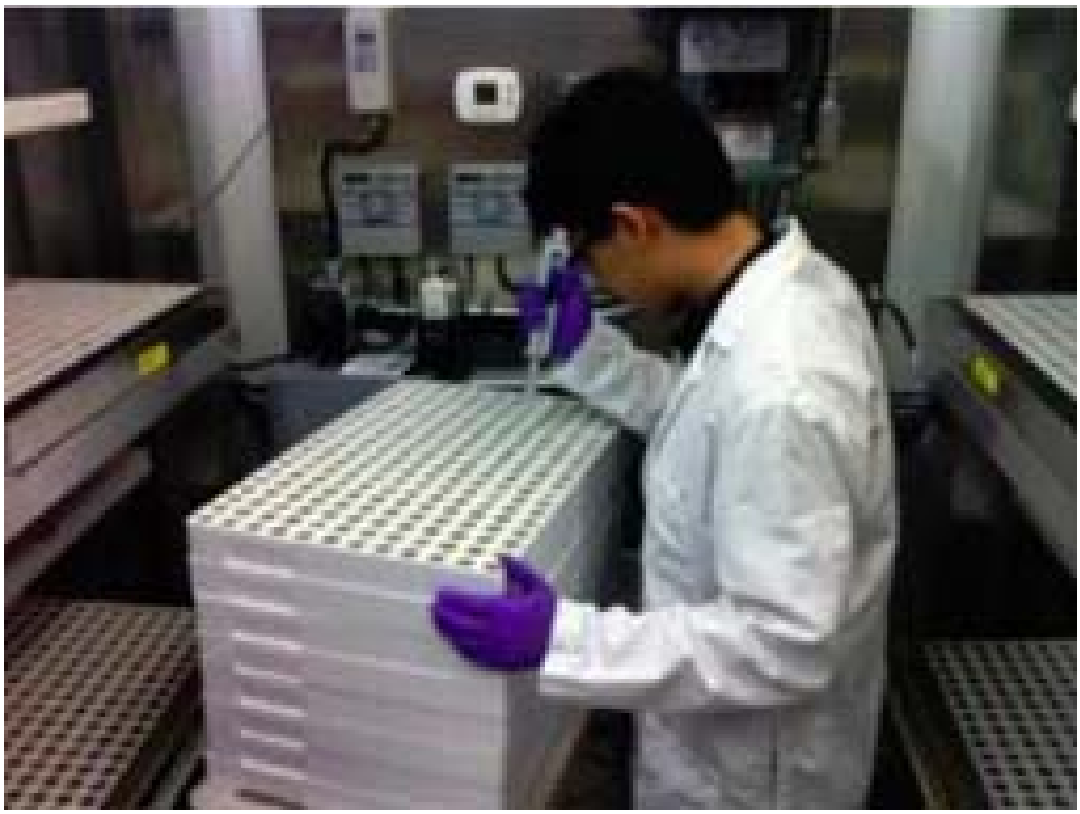
Dual 3 Tier Design

Full Configurable Design

Separate Irrigation System

LED Light Technology

Exhibit G: Seed Sowing Process

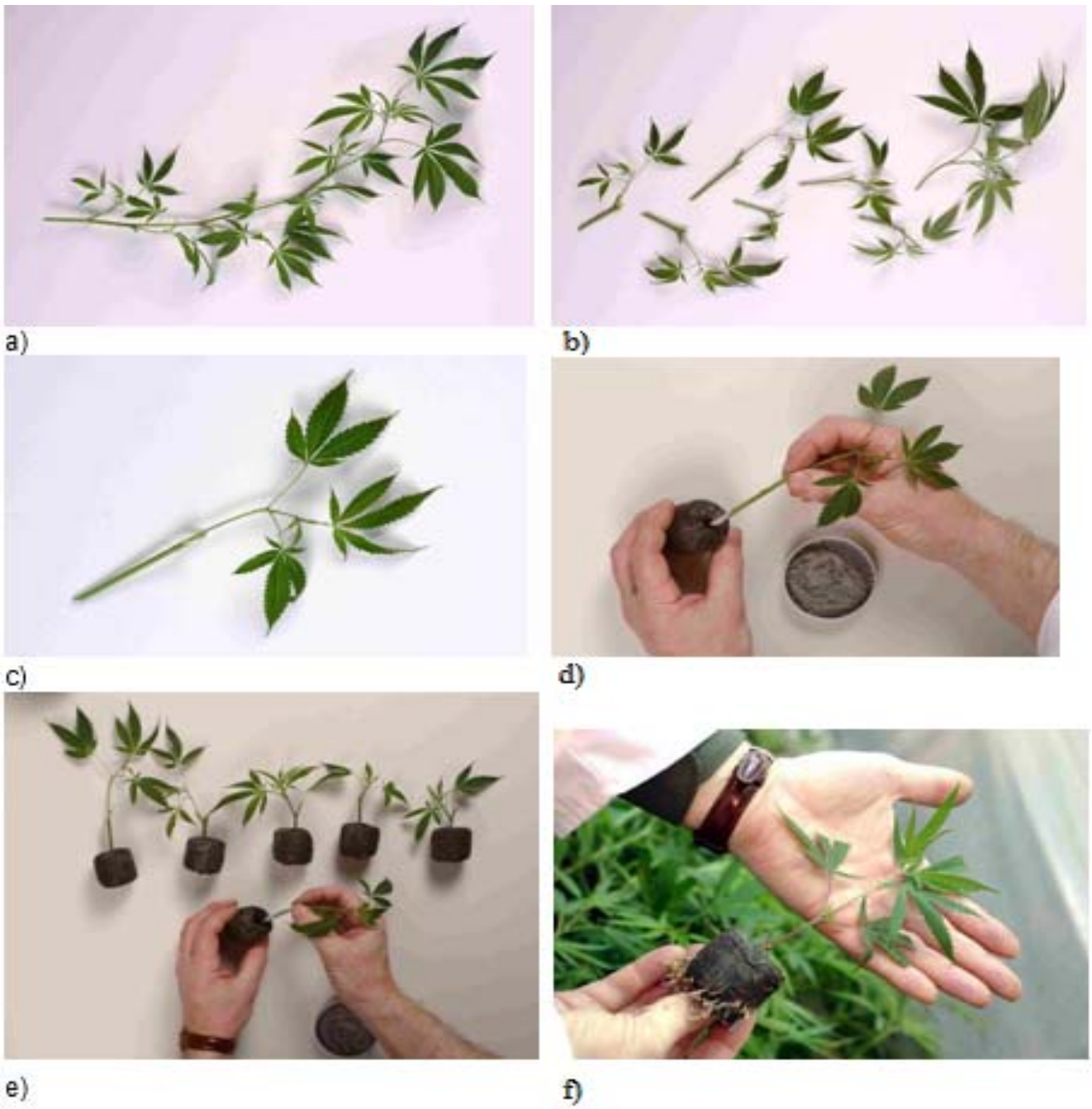


6.6 Production of Cuttings (Clones):

Once a single harvest from seed derived plants reaches the end of the vegetative cycle, clones can begin to be harvested to become mother plants and future plants. Branches of vegetative material will be removed from plants producing ample numbers of axial branches. These branches will be cut into sections, each carrying one or more nodes and at least one internode. The lowest part of the stem will then be dipped in rooting liquid containing 0.24% 1-Napthaleneacetic acid and 0.013% 3-Indolebutyric acid and then promptly into a very moist Rockwool plug **(Exhibit H).**

The plugs will be inserted into a tray and taken to the Green Pod. They will be grown in the same self-contained environment as the seedlings with identical irrigation strategy, light levels, and climate. Successful cuttings will typically produce sufficient roots within fourteen days to enable transplanting. During propagation a unique, water-proof RFID tag will be attached to the propagation flat of each batch of clones to track its progress as a as a part of a batch number until it reaches the height of 18 inches in vegetation when it will be assigned a unique numerical plant identification number. At this point a unique, water-proof RFID tag will be placed around each individual clone to track its progress as a single plant in conjunction with its plant batch number allowing the batch to be tracked from seed to sale.

Exhibit H: Cuttings (Clone) Transplanting Process



A) Vegetative Marijuana Branch:
B) Is cut into sectionals
C) Each cutting has been cut leaving approximately five centimeter of stem below a single axial bud up to one centimeter above.
D) The base of the cutting is dipped into the rooting powder.
E) And placed into the Rockwool plug which is then placed into the tray.

F) After two weeks roots are protruding from the Rockwool plugs and the cutting is ready to be planted.

6.7 Nurturing Vegetative Growth of Seedlings and Cuttings:

Once seeds/clones complete the propagation phase, they are transplanted in the potting area and from there they are rolled on carts to the corresponding vegetative zones. Normally, all high-THC plants will be planted in 4" blocks (64 in^3) of an inert Rockwool growth medium. High CBD plants varieties will be planted in 3" (27 in^3) blocks of the same medium. The climate of the vegetative zones will be maintained between 70-80F and relative humidity between 40-50% to ensure plant health and mitigate the risk of contamination.

6.8 Induction and Maintenance of Flowering

Plants are then placed on rolling carts and wheeled into a flowering room and placed into Flowering Zone Gutter system to begin the short day length cycle of 12 hours per day. Utilizing a high pressure fog evaporated cooling system, the climate of the Flowering zone will be maintained between 65-80F and relative humidity between 30-50% to ensure plant health.

During this period crops will be spaced at a density of 1 plants per 25 square foot (THC chemotype) or 1 plant per 16 square foot (CBD chemotype). Plants will be subjected to 800 umols of light from the sun 12 hours a day. The response to this 12 hour day length change will compel the plants to commence flowering within seven to fourteen days, this is known as the stretch period. The short day length will be maintained for the entire flowering period, which typically lasts approximately eight to ten weeks depending on the cultivar. Only green lights will be employed when employees will enter the crop during the daily dark cycle to conduct work because plants do not absorb the green light spectrum therefore it will not impede the flowering process.

Priva

- Brain of the Cultivation & Processing Center
- Provides state-of-the-art industrial monitoring and automated control applications.
- Full Control over nutrient injection equipment, irrigation systems and watering schedules, decagon sensors, and HVAC climate systems.

Decagon Sensors

Provides precise measurement of the following plant variables:

- Plant Root Temperature
- Water pH
- Nutrient levels
- Canopy Daily Light Integral (mol)

6.9 Harvesting:

Plants will be harvested by cutting the stems just below the lowest side-branch and each individual branch will be hung on a clean and sanitized stainless steel rolling rack. Quick and efficient harvesting is key as respiration could rapidly generate heat within piled fresh material. Loaded carts will be brought immediately the trimming

chambers to avoid heat-induced catabolism. The hanging plant material will then be placed into bins sorted by cultivar and weighed for processing.

Harvest is a stage in the product life cycle that is very vulnerable to contamination since the plants are being cut from there nutrient and water source, handled heavily, and moved around. This time is critical to process the flowers prior to drying as they become much more susceptible to damage and contamination once dry.
Once the entire batch (zone) has been harvested, the area and gutters that will then be vacant will be extensively cleaned and sanitized. All harvested products will be taken to the drying room for slow dehydration.

All non-usable plant material and growing medium will be placed in bags, assembled on pallets in the greenhouse hallway and forklifted to the secure waste storage area of the head house. All infested, damaged, moldy or otherwise contaminated or unusable product will be sealed an air tight container and quarantined in the head house waste disposal area to be weighed, tested, and tracked in "State Selected Software" for compliance and audit purposes. Once inventoried all this material will be rendered unusable through grinding and mixing with media and other debris as outlined in the disposal regulations.

6.10 Garbling/Manicuring

Garbling is the first step of the processing and manufacturing process. It begins with employees leaving their respective locker rooms in their color coded jumpsuits and pass through an air-shower **(Exhibit K)** to remove all outside contaminates and adulterants from entering the controlled environment processing center. Processing is the most labor intensive aspect of the entire manufacturing operation because of the need of manual trimming to ensure that quality dry flower buds are always made available for the patients **(Exhibit L)**. Mechanical trimmers will be utilized to minimize the amount of labor but are not used to complete this process. A strong cleaning and sanitation protocol is crucial to ensure the processing environment is sterile and the chances of cross contamination are low. No processor can be allowed to enter past the locker without a clean suit, shoe covers, washed, sanitized, and gloved hands, and only after finally passing through the air shower for 30 seconds.

Once all the recently harvested material is weighed in the bins, the plant material will be processed in segregated batches of approximately 25 pounds. The first step of processing is garbling which is the final step in the preparation of a crude drug and involving the removal of extraneous matter such as other parts of the plant, dirt and added adulterants. In company's highly bio-containment facility minimal adulteration or contamination with dirt will arrive. More pertinently, the presence of low-potency stem material such as fan leaves is undesirable and all material assessed as more than 2 mm in diameter and possessing no or minimal cannabinoid content will be removed. This unusable material will be bagged, weighed, input into "State Selected Software" and brought to the head house waste storage room.

The next step of the manicuring process involves separating the excess usable trim from the flower buds. This step will involve manual trimming using hand tools after the plant material is first run through a trimming system to efficiently remove excessive trim while not harming the high cannabinoid content trichomes of the flower buds and sepals. Once the flower buds finish their pass through the trimming system and are placed into the sanitary bin they are brought to the inspection table for final manicuring.

Exhibit K: Air-Shower

Exhibit L: Garbling Process

6.11 Drying Process

The drying chambers will be constructed as white rooms (also known as clean rooms). The nearly air tight room, will be highly climate controlled with a HEPA filtered HVAC system controlling the air temperature and humidity. Depending on what stage of the 4-10 day drying process, the climate will be maintained at 60-70F and 30-40% relative humidity. The dry rooms will be kept dark at all times and only green light (which plants do not absorb) will used when employees have to enter the drying rooms. Re-entering these environmentally controlled rooms will only be done for purposes of inspecting the progress of the drying phase and to remove product from the drying rooms for packaging/curing and great care will be taken to prevent contamination.

It is the responsibility of the shift Agent-in-Charge to maintain the drying rooms in clean and sterile conditions. The Agent-in-Charge will ensure the atmospheric controls are primed the day of the harvest so the materials go into the room at the proper conditions.

The harvested and trimmed marijuana plants will be moved immediately to the primed drying room. Once there, crop drying will commence immediately with most of the moisture being pulled from the plant material within the first 24-48 hours. There will be no periods of time when warm and wet conditions will be permitted in this area, because this can foster growth of bacteria and fungus.

Plants in the drying chambers will be hung to from sanitized stainless steel wire as seen in Exhibit M. Industrial dehumidifiers will be used to lower air moisture and horticultural fans will be used to maintain air circulation. The air surrounding the chamber will be conditioned as appropriate to ensure that waste heat from the dehumidifiers does not raise temperatures within the chamber above 70F.

Freshly harvested material possesses an aqueous content of approximately 80% water weight. The first 50% of the plant's water weight will be removed within 48 hours

to lower the chance of mold growth. The crop will be considered dry enough for curing when below 15% water weight. At this point, the crop will be clearly crisp to touch, the inflorescence tissue closest to the stem feeling dry and the floral material would readily pull away from the stem without excessive force.

This means, the plant material has reached its optimal dryness level and is ready to be taken to curing. New Parchment paper will be placed on top of a scale and a processor will proceed to lay approximately one pound of dry, botanical material on the scale. When one pound is achieved, the parchment paper will be used to easily insert the plant material into a 2.5 gallon air-tight glass apothecary jars. Four jars will be filled and then the jars will be inserted into a bin with foam protection for support. The bin will be placed on a cart and once the cart is full it will be wheeled to the climate controlled vault where the bins will be placed on a rack in the curing section of the vault.

The excess trim obtained during the manual and automated manicuring process once dry will be bailed in sanitary plastic bags by batches. This bag will be brought to the milling and decarboxylation lab for extraction and infusion into non-smokable products such as tinctures and "functional food".

At the end of the drying processes all infested, damaged, moldy or otherwise contaminated or unusable product will be sealed an air tight container and quarantined in the head-house waste disposal area to be weighed, tested, and tracked in "State Selected Software" for compliance and audit purposes. When workers successfully remove all the plant material from the drying room, a thorough cleaning will commence to sanitize the entire drying room to prepare it for the next harvest.

6.12 Test Sampling

6.12.1 Sample preparation for useable marijuana

Before processing can occur, batch test samples will be taken to assure the plant is of the highest quality and will pass all the residual pesticide, microbiological, mycotoxin, as well as active ingredient potency test. Established methodologies exist for preparing a sample of useable marijuana for testing. These methods vary slightly based on the intent of the test (e.g. detecting pesticides, or potency, or microbiological, and mycotoxin). As all inventory transactions are tracked and logged in "State Selected Software" samples sent to the lab, or inventory removed from the system for any reason, are tracked in un-modifiable log entries. Along with any inventory or plant removal from "State Selected Software" notes must be applied. The batch that the inventory is removed from is recorded, along with date and time and person authorizing the inventory adjustment.

6.12.2 Selecting the sample

Marijuana inflorescence (flower buds) or trim is sampled when performing testing for potency, microbiological, and mycotoxin test. The flowers of the plant will be used for pesticide testing. Commonly the leaves may be used for pesticide testing however it is our goal to ensure patient safety and therefore it only makes sense that we test the actual products going to patients

A test specimen will be comprised of inflorescence taken from a batch of plants, and a representative sample of 25 grams per 25 pounds. It's imperative that samples are randomized in accordance to greenhouse area as well from different heights on the plant in order to obtain representative results for the batch as a whole. This involves marking during the harvest process which plant material will be sampled after drying.

Samples will be sent to the head house lab to log and be packaged for retrieval by the state authorized 3rd party lab or delivery to said lab. Utilizing the company's own HPLC and GC-MS testing equipment, The Company will also conduct its own in-house quality control testing in its lab after the first year of production. As described below, once the dried plant material is processed and sent to the curing vault it will remain there in quarantine until the lab test results are received and reviewed.

Samples will be collected in accordance with the following procedures:

(1) The containers selected for sampling will be cleaned when necessary in a manner to prevent introduction of contaminants into the component, in-process material, marijuana or marijuana-derived product.

(2) The containers will be opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, in-process materials, marijuana or marijuana-derived product.

(3) Sterile equipment and aseptic sampling techniques will be used when necessary.

(4) Where appropriate for the purpose of the sample and the nature of the material being sampled, sample portions are removed from the top, middle, and bottom of containers. Such sample portions may be composited in forming the representative sample, or may be tested separately, as appropriate to the purpose.

(5) Containers from which samples have been taken will be marked to indicate that samples have been removed from them.

(a) Using the "State Selected Software" software labels will be printed and sample containers will be labeled with the following information:

(1) Name of the item sampled;

(2) Batch number of the item sampled;

(3) Container from which the sample was taken, or for samples taken directly from the production line, the equipment line and time at which the sample was taken.

(4) Date on which the sample was taken;

(5) Name of the person who collected the sample; and

(6) Quantity and unit of measure of the sample.

(b) Each sample removed from a batch will be recorded in the inventory system.

(c) The quantity of the sample used for each test will be of sufficient size or number to ensure a representative of the batch or lot. While each test requires

(1) Botanical flower: 25 grams for each 25 pounds of marijuana flower batch.

(2) Marijuana concentrate: 1 gram of concentrate per concentrate batch from the Apeks Sub-critical 5000-20L system.

(3) Marijuana "functional food": one finished product per batch

(d)A reserve sample will be prepared from the representative sample of each batch of shelf-stable component, marijuana or marijuana-derived product.

(e)Reserve samples will consist of at least twice the quantity necessary for tests and examinations to determine whether the shelf-stable component, marijuana or marijuana-derived product meets established critical quality specifications. However, where state law limits the amount of marijuana and marijuana-derived product permitted to be kept on hand, operations may keep smaller amounts in reserve if necessary.

(f) If a botanical sample of marijuana does not pass the microbiological, mycotoxin, pesticide chemical residue or solvent residue test.

1) If the sample failed the pesticide chemical residue test, the entire batch from which the sample was taken shall, if applicable, be recalled and disposed of.

2) If the sample failed any other test, the batch may be used to make a CO2 or solvent based extract. After processing, the CO2 or solvent based extract will still pass all required tests

"State Selected Software" batch sales report allows for any batch to be traced to all customers that received product from a batch, in any form. Reporting functionality also allows a batch to be traced back to its harvest, and all plants included in that harvest, in order to examine any processes carried out with the cultivation or post-harvest process relevant to a batch in question. Disposal processes can be documented through "State Selected Software's distribution module.

6.12.3 Manufacturing sampling requirements

Batch of component, marijuana, or marijuana- derived product will immediately be made available after product drying or prior to manufacturing at the cultivation center for an employee of an authorize laboratory to select a random sample, which shall be tested by the approved laboratory for;

1) microbiological contaminants;
2) mycotoxins;
3) pesticide active ingredients;
4) residual solvent; and
5) purposes of conducting an active ingredient analysis.

The approved laboratory most likely will dispose of any marijuana infused product upon the completion of the test.

6.13 Third Party Testing

All Product testing will be done by state certified laboratories. Extensive logs track each action performed at the cultivation center and with State Selected Software" testing results API, testing results can be automatically sent from the testing lab to the "State Selected Software's software, eliminating the possibility of manual data entry errors.

6.13.1 Pesticides:

We will ask the lab to take our flower and trim sample and perform an ASAP probe screen, followed by a Solid Phase Extraction (SPE) phase, and ending with Liquid Chromatography-Mass Spectrometry test to determine that the sample meets the acceptable standard for a pesticide residues in any food items set forth in subpart C of USEPA's regulation for Tolerances and Exemptions for Pesticide Chemical Residues in Food (40 CFR 180 (2014)).

6.13.2 Microbiological:

We will ask the lab to take our sample, extract the sample in butter, place the extract in organism specific trays and once the trays have set the tray colonies are counted to assure that the samples meets the recommended microbial and fungal limits for marijuana products in colony forming units per gram (CFU/g) set out in the AHP American Herbal Pharmacopoeia Monograph.

6.13.3 Mycrotoxin/Aflatoxin:

We will ask the lab to run our sample through an aflatoxin column to trap the aflatoxins for analyze in a fluorometer to determine that sample meets the following standard;

6.13.4 Potency

Ultra-High Performance Liquid Chromatography (UPLC) will be asked to be used to test and analyze nine of the known cannabinoids and most importantly the following cannabinoids;

i. delta-9-tetrahydrocannabinol (THC);
ii. tetrahydrocannabinolic acid (THCA);
iii. cannabidiol (CBD);
iv. cannabidiolic acid (CBDA);

6.13.4 Residual Solvent:

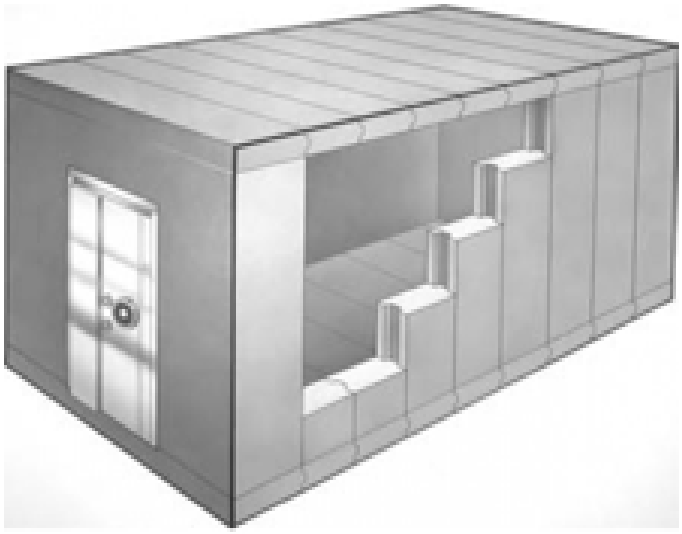
We will ask the lab to take our marijuana concentrate sample extract and homogenize the sample, place it in a Headspace-gas chromatography system to assure the sample solvent is less than 10 ppm.

6.14 Curing in Climate Controlled Vault Storage

Curing and finished packaged product is all done in the DEA Schedule 1 Climate Controlled Vault **(Exhibit N)**. Curing is one of the most vital stages of the entire manufacturing process and plays a critical role in determining the cannabinoid make-up of each flower. Curing conditions will ensure that the product neither dries nor moistens while temperatures are between 50-70F with a relative humidity between 30-40%. Because some cannabinoids are sensitive to photo degradation the vault's main source of light will be green bulbs and the glass jars will be opaque.

Post-drying curing will commence at a moisture level between 8-15% when the product is near dry. Curing will finish at a product moisture content that is desired for packaging which is between 6-10%. This process typically takes an additional 7-14 days after drying depending on the cultivar.

Exhibit N: DEA Schedule 1 Vault



Class I Vault Specification:

- GLA V Vault Door with Group 1-R combination lock and UL Listed Reinforced Modular walls, floor and ceiling Provide:
  - 30 man minutes against Torch and tool entry,
  - 20 man hours against lock manipulation,
  - 20 man hours against radiological attack.
- Kay pad and alarmed & infrared sensored perimeter walls will alert all security levels of unauthorized entry.
- Self-closing and self-locking "Day Gate" provides added internal security when door is opened frequently throughout the day.
- HVAC Ready Vault provide precise climate control.

Vault Racking System

- Barcoded Racking allows for easy tracking of finishing and finished product inventory.
- Provides clear delineation between finishing curing product and finished packaged product.

"Day Gate" Internal Secure Door

6.15 Packaging Process

The processing stage, like harvest, is vulnerable to contaminants. The climate of the processing and packing rooms will mimic the ideal conditions for the product inside its sealed package. Below is a list of protocols that the company will put into place to assure a high quality packaging operation. Section 8 provides an extensive overview of the full packaging and labeling process controls.

a) The processing and packaging room will be entirely enclosed to facilitate climate control which is needed to maintain optimal packaging moisture levels **(Exhibit O)**.

b) The room and its entire infrastructure will be easy to clean and sterilize. Stainless steel tables, floor drains and Mar-lite paneled walls will aid in the ease of cleaning and sterilization.

c) Filtered positive air pressure over work areas will reduce the risks of contamination and worker exposure to breathing dust particulate from processing the product.

d) Clean-suits, masks, and gloves are mandatory in the processing phase of the product life cycle, as it is the most vulnerable point, as well as the last chance to detect contamination prior to packaging.

e) Curing will feed directly into packaging to prevent overhanding of product and reduce exposure to contaminants.

f) Each product intended for market will be registered on the documentation to be supplied by the state and associated fees paid in advance. Great care will be taken to ensure usable products and by-products are placed in clean and sterile, pharmaceutical containers that are child-proof. All products leaving the facility for sale or further processing will be labeled as follows (not to include products rendered unusable intended for disposal):

    1. The name and P.O. Box of the registered cultivation center where the item was manufactured;
    2. The common or usual name of the item and the registered name of the marijuana product that was registered with the regulatory body.
    3. A unique serial number that will match the product with a producer batch and lot number to facilitate any warnings or recalls the producer deems appropriate;
    4. The date of final testing and packaging, if sampled, and the identification of the independent testing laboratory;
    5. The date of manufacture and "use by" date;
    6. The quantity (in ounces or grams) of marijuana contained in the product;

7. A pass/fail rating based on the laboratory's microbiological, mycotoxins, and pesticide and solvent residue analyses, if sampled;

g) The product will be at an optimal moisture level (approx. 6-10% for marijuana flowers) prior to entering the package and the processing room environment will not add moisture. The packaging material will be acclimated to the processing room's ideal temperature and humidity (approximately 30-40% humidity and 60-70 degrees Fahrenheit).

h) The product will be weighed and inserted into its respective package.

i) Each package is barcoded and the barcode on the package is scanned to isolate the proper inventory package. Sealed package are weighed on integrated scales and the gross package weight is sent directly into "State Selected Software", enabling easy comparison to stored weights.

j) All inventory adjustments are captured and stored within "State Selected Software" allowing for real-time reporting to identify any loss, as well as reason for loss.

k) "State Selected Software" tracks and labels two weights for each package of marijuana. Net weight is the weight of the marijuana itself contained within the package. Gross weight is the final weight on that marijuana in its sealed package. This allows for easy reconciliation weights to be taken of any package at any time without the need to open the sealed package.

l) Once the product is packaged in the sealed child-proof pharmaceutical container and the shrink sleeve with accompanying tamper evident seal applied and adhered by the steam tunnel, it will be stored in the clean, cool, and dark section of the vault designated for finished products.

m) The finished product shelf-life will benefit from low temperatures and low light with low-to-moderate humidity.

1. A list of the following ingredients, including the minimum and maximum percentage content by weight for subsections
    i. delta-9-tetrahydrocannabinol (THC);
    ii. tetrahydrocannabinolic acid (THCA);
    iii. cannabidiol (CBD);
    iv. cannabidiolic acid (CBDA); and
    v. Any other ingredients besides marijuana.

2. The acceptable tolerances for the minimum percentage printed on the label shall not be below 95% or above 105% of the labeled amount.

n) Prior to moving packages of marijuana from the packaging area to the shipping bay, a distribution document will be created in "State Selected Software". The distribution will record the current location and status of the packages, such as "in-

transit" or "received". "State Selected Software" will also create a transport manifest, for the package distribution. The manifest will contain details such as time of departure, time of arrival, product and product weight, route to be travelled, origin and destination addresses, and vehicle and employee information. This document can be e-mailed, printed, or produced virtually, on a mobile device such as a tablet, from within "State Selected Software" and sent to the recipient party such as a dispensary. Each distribution of packages will have a physical copy of the manifest with it at all times.

Exhibit O: Clean Room Packaging

6.16 Waste Disposal

6.16.1 Compostable Material

Marijuana waste and plants that do not meet standards for health, quality, and viability are destroyed. This includes any plant that may be diseased, damaged, or otherwise substandard. Only a limited number of authorized staff are permitted to destroy plants. These staff members record the destroyed plant weight and the reason for destruction in "State Selected Software". All compostable material is composted on-site to reduce the amount of waste for disposal. All plant waste is mixed, fifty-percent (50%) by volume, with an approved inert material, and disposed of by an approved and licensed waste management company.

All non-usable plant material and growing medium will be placed in bags, assembled on pallets in the greenhouse hallway and forklifted to the secure fenced waste storage area of the head house under the supervision of the Director of Cultivation Operations Agent-In-Charge. All infested, damaged, moldy or otherwise contaminated or unusable product will be sealed an air tight container and quarantined in the head house waste disposal area to be weighed on the head-house scale, tested, and tracked in "State Selected Software" for compliance and audit purposes. Once inventoried all this material will be rendered unusable through grinding and mixing with media and other debris as outlined in the disposal regulations within the fence and electronically and camera monitored waste disposal area.

Four days prior to the established harvest date, the Director of Cultivation Operations Agent-In-Charge will notify the regulatory body through the traceability system that within the next 10 days marijuana waste will be rendered unusable. A few authorized employees will bring the botanical waste material to the chain link waste disposal area by only, where under supervision of Director of Cultivation Operations Agent-In-Charge and under camera surveillance, the waste will be weighed on the head-house scale and recorded and entered into "State Selected Software". Waste produced during or after the harvest can be isolated within the software with disposal date, weight and method tracked and logged. All 'types' of product produced from the harvest are tracked independently including waste (stem, stalk, root ball, etc.) which enables individual distinction in the tracking system.

Because the company's growth medium is reusable Rockwool, botanical marijuana waste material will be mixed and ground with compostable material purchased from the Compost Supply Company. The mixing and grinding process will occur in 55 gallon drums with 50% non-marijuana waste by volume mixed with marijuana botanical waste. The 55 gallon drum will be -/placed on the head-house scale and filled with non-marijuana compostable material until it reaches a slighter higher volume than marijuana waste bag that will be dumped into the 55 gallon drum into order to assure at least a 50% by volume marijuana and non-marijuana compost waste. The material will then be rendered by a motorized mixing unit **(Exhibit T)**. The newly ground material is capped and locked in the head-house locker.

Once rendered waste material is ready for disposal at least 7 days after the regulatory body had been notified through the traceability system, the drum will be brought outsize and with use of a forklift turned upside down into a highly secure and lockable

commercial cart. The drum will be removed and the commercial cart locked. All of this will occur on camera. A composting company will be notified a day prior to the commercial cart being filled, so that the same day it is filled they will pick-up the compost material, further preventing potential theft. The composting organization will bring the compost to their compost site to be re-used for agricultural needs at a later date thus reducing The Company' overall waste production.

6.16.2 Non-Compostable Material

Processed marijuana material from the extraction lab will undergo a very similar disposal protocol as compostable waste except due to its residual solvents, the material is non-compostable.

Four days prior to the established extraction date, the Processing Manager Agent-in-Charge will notify the regulatory body through the traceability system that within the next 10 days marijuana waste will be rendered unusable and disposed.

Once the CO2 sub-critical and ethanol extraction process is completed, a laboratory technician under supervision of the Processing Manager Agent-in-Charge will securely bag the excess waste and weigh it, print a new disposal label and scan the information into the "State Selected Software" software. The software with associate the waste the waste to its specific marijuana batch and allow the disposal date, weight and method of disposal tracked and logged. Once this process is complete and the weight is established, the lab tech will call for the Processing Manager Agent-in-Charge to have a 55 gallon drum prepared with equal parts by volume of soil delivered by the Compost Supply Company. Once the drum is prepared, the processing waste will be brought directly to the waste disposal area by the Processing Manager Agent-in-Charge for him to supervise the rendering and grinding of the process waste into the 55 gallon drum by an authorized employee.

The material will be rendered by a motorized mixing unit like one used for botanical compostable waste. The newly ground material is capped and locked in the head-house locker. Once the rendered waste material is ready for disposal at least 7 days after the regulatory body had been notified through the traceability system, the drum will be brought outside and with use of a forklift turned upside down into a different highly secure and lockable commercial cart than the one used for compostable waste. The drum will be removed and the commercial cart locked. All of this will occur on camera, including the cart's pick-up by a certified composting company.

6.16.3 Hazardous Waste

If any event hazardous waste will be disposed of a similar protocol will be undertaken and will be disposed of in a manner consistent with federal, State and local laws. An example of hazardous waste would be unused pesticides. Disposal of all unused pesticide product shall be performed in compliance with all State and federal laws and regulations, which require compliance with all directions on the product label.

6.16.4 Liquid Waste

Liquid waste from a cultivation center shall be disposed of under a similar protocol in compliance with the Environmental Protection Act and administrative rules.

Section 7: Quality Assurance Plans

Dispensary Operations:
Quality and Error Management in the Facility

Sponsored By: Kinex Supportive Pharmaceuticals Dispensaries Team

POLICY:

(a) Kinex Supportive Pharmaceuticals Dispensaries will commit to a process that will identify and addresses concerns related to the quality and safety of drug inventory and distribution; as well as quality of service.

(b) Kinex Supportive Pharmaceuticals Dispensaries continuously monitor dispensing of products for accuracy within the Dispensary including tracking errors, reporting errors, and analysis of error data reports.

(c) Kinex Supportive Pharmaceuticals Dispensaries ensure the proper reporting of quality and errors to the quality management committee.

PROCEDURE:

A. Each week a manual and full inventory is completed by the Pharmacist in Charge (PIC). A physical inventory report is printed that sorts inventory by the inventory number in a blank format. The PIC then manually counts each inventory item and denotes it on the physical inventory sheet. After each product is accounted for, the inventory report is printed to show current on hand inventory and the numbers are matched to show any discrepancies. This weekly inventory will show any discrepancy in the quantity of products billed to orders dispensed. Reporting can then be viewed to assess the inventory errors.

B. If there is a discrepancy in the inventory, a drug usage report and inventory quantity adjustment report is created to view which patients have received the drug in question within the inventory period. Based on the quantity discrepancy, patients' billing records and a patient call is placed to ensure the accuracy of their medication. If an error is discovered, a new medication arrangement is set up. A dispensing error may be brought about by a patient, or member of the Dispensary staff. In event of a dispensing error, the patient will be called and asked to relay the information necessary off of the label. These errors are tracked by the PIC within a file containing the medication and/or notation of what the issue was and how it was resolved. Additionally, the patient in question will have progress notes detailing the situation. Any suspected or confirmed error in dispensing will be reported to the Director of QA and the COO, which will then be discussed at the Quality Management Committee meeting. Each time an error is discovered or brought about, a root cause analysis is completed to determine how the error has happened. Errors are then analyzed based on current procedures by the Quality Management Committee and necessary procedure changes may be employed as deemed by the meeting.

C. Weekly inventory errors and discrepancies are brought to the Director of QA each week and discussed in the Quality Management Committee meeting when appropriate.

Dispensary Operations:
Oversight of Dispensary Safety

Sponsored By: Kinex Supportive Pharmaceuticals Dispensaries Team

POLICY:

A. Pharmacists at Kinex Supportive Pharmaceuticals Dispensaries will have appropriate management oversight of dispensary operations. There will be direct accountability by the Pharmacist at Kinex Supportive Pharmaceuticals Dispensaries.
B. Pharmacists and dispensary technicians will have explicit roles and responsibilities for dispensing.
C. Dispensing and preparation of medications will be directly observed by a pharmacist.
D. Kinex Supportive Pharmaceuticals Dispensaries will ensure that the dispensing of medications complies with NYS DOH imposed restrictions on particular product, as applicable.

PROCEDURE:

A. The Supervising Pharmacist (SP), or Pharmacist in Charge (PIC), will have the ultimate responsibility for the supervision of the roles and responsibilities of each dispensary staff member.
B. The staff pharmacist responsibilities include, but are not limited to, verifying certifications for accuracy, dispensing, therapeutic interactions, therapeutic indication appropriateness, counseling, and verbal communication to providers to obtain address certifications and clarify certifications in question. All roles except for the final complete prescription check may be delegated with direct oversight to a licensed dispensary intern. All dispensary technicians must be certified technicians. The pharmacist may delegate the roles of filling, counting, labeling, and compiling paperwork. Other roles may be delegated as necessary and as appropriate.
C. Throughout the workflow, the dispensary technician is monitored for accuracy, proper handling, and appropriate workflow by a pharmacist
D. Self-imposed manufacturer restrictions on particular product are monitored by the Pharmacist in Charge, and are labeled appropriately in the location the medication is stored. Any special handling or dispensing of products will be conveyed to all dispensary staff by the Supervising Pharmacist.

Dispensary Operations:
Certification Dispensing by Pharmacist

Sponsored By: Kinex Supportive Pharmaceuticals Dispensaries

POLICY:

A. Kinex Supportive Pharmaceuticals will match the certification to the correct patient, route of administration, dosage and strength, administration schedule, and medication.
B. Appropriate patient education materials will be included within medication packages when appropriate.

PROCEDURE:

A. When dispensing a certification the Pharmacist ensures that the certification being dispensed is for the correct patient, correct route of administration, correct dosage, correct strength, correct administration schedule and time, and the correct medication/drug.

Dispensary Operations:
Dispensary Operations Service Scope and Criteria

Sponsored By: Kinex Supportive Pharmaceutical Dispensaries

Policy:

A. Kinex Supportive Pharmaceutical Dispensaries will ensure that medication accessibility and availability is promoted to comply with patient's needs.
B. Kinex Supportive Pharmaceutical Dispensaries continuously monitors performance to promote patient satisfaction.
C. Kinex Supportive Pharmaceutical Dispensaries continuously make improvements to meet the growing needs of our patients.

Procedure:

A. Kinex Supportive Pharmaceutical Dispensaries provide and medications to patients with complex chronic disease states.
    i. The services we offer include, but are not limited to:
        a. Medical device training
        b. Medication counseling
        c. Certifications retrieval
        d. Adherence monitoring
        e. Provider relations
    ii. Patient Accessability:
    Kinex Supportive Pharmaceutical Dispensaries measures medication accessibility through a variety of ways. We measure call metrics such as abandonment rates, time to answer, and call frequency. We offer 24 hour access to a pharmacist to address any patient concerns. In addition, we continually evaluate the hours our dispensary is open to ensure that we are covering all patient needs. Kinex Supportive Pharmaceutical Dispensaries sends out an annual patient satisfaction survey measuring ease of placing orders, timeliness of orders, accuracy of certifications filling, courtesy of the customer service reps, ability to answer phone calls quickly, and overall satisfaction with the dispensary service.
B. In order to measure how well Kinex Supportive Pharmaceutical Dispensaries is meeting the needs of our patients, surveys are sent out annually within medication delivery supplies. This survey includes a return envelope to assist the patient's response.
C. The responses included within the mailed survey are compiled and then reviewed. Adjustments may be necessary to meet different patient's needs; which can be made after survey results.

Dispensary Operations:
Certification Intake Process

Sponsored By: Kinex Supportive Pharmaceuticals Dispensaries

POLICY:

A. Kinex Supportive Pharmaceuticals Dispensaries will ensure proper receipt of each certification, verifying the prescriber, patient, and/or caregiver submits them in accordance with good practice and state laws when necessary.
B. Safety Guidelines will be in place throughout the certification intake process.
C. Kinex Supportive Pharmaceuticals Dispensaries will maintain patient health history, medication history, allergies and past sensitivities, and any other pertinent information necessary to consult with the prescriber and counsel the patient and/or caregiver. Additionally, high risk groups will be identified; as well as verification of consumer's eligibility.
D. Kinex Supportive Pharmaceuticals Dispensaries will always comply with State laws.

PROCEDURE:

A. A provider must send certifications through state system. Once the certification is received into the system, it is assigned to the correct patient. Patients or caregivers may contact us and we will reach out to their provider on their behalf for a certification that is questionable. We will comply with communication restrictions as they are further developed by DOH.
B. The patient is verified by checking at least two identifiers including name, date of birth, address, and phone number. The prescriber is verified by license number, NPI, or DEA number, along with the phone or fax number that the certification may include. Possible caregivers for the patient are identified after speaking to the patient directly and having them agree that specific individuals are aware and a part of their ongoing care. The name of other responsible individuals in the patient's care is then placed into the patient profile with their relationship to the patient noted. (Must be certified caregiver under MMJ program)
C. To improve patient safety no medication is discussed until certification is determined to be within complex relating to the recommended dosing and indication, as well as appropriate for the particular patient case.
D. When Kinex Supportive Pharmaceuticals Dispensaries first contacts the patient, all demographic information is compiled. This information includes, but is not limited to, address, phone number, other caregivers, allergies, medication intolerances, medication history, and comorbidities. Counseling by a pharmacist or pharmacy intern is offered with each fill of a certification.

Some patient's may be deemed as high risk due to other comorbidities or age. This may include patients who have a potential drug-disease state interaction, or may be very sensitive to medications adverse effects due to age. Other risk stratification may be due to handling of medication. A patient's eligibility for services is determined by a legal and valid certification

E. Kinex Supportive Pharmaceuticals Dispensaries follows all state pharmacy laws.

Dispensary Operations:
Certification Order Review and Verification by Pharmacist

Sponsored By: Kinex Supportive Pharmaceuticals Dispensaries Management Team

POLICY:

A. Kinex Supportive Pharmaceuticals Dispensaries will verify the source of the certification.
B. Kinex Supportive Pharmaceuticals Dispensaries will ensure the certification is legible, and will clarify the certification when necessary.
C. Kinex Supportive Pharmaceuticals Dispensaries will resolve all certification discrepancies.

PROCEDURE:

A. Each certification is verified by a Pharmacist prior to dispensing.
B. In the event that there is a discrepancy on the certification, or a certification is questionable, the Pharmacist will contact the prescriber's office to clarify the issue in question. Once clarification is received, the notation is made on the certification including the prescribers name or agent of the prescriber clarifying the order, date, time, and initials of the Pharmacist. A decision must be made to contact the DOH if corrections need to be made. In no case will a pharmacist dispense any product without complete compliance with the State Laws, and when there is doubt they must hold the dispense until the state has made a clarification or correction.
C. Once a certification clarification is made, the medication is dispensed to the patient. The Pharmacist In charge must review the process and notate in the record that the correct action was taken

Dispensary Operations:
Labeling, Dispensing, and Packaging Process

Sponsored By: Kinex Supportive Pharmaceuticals Dispensaries Team

POLICY:

A. Kinex Supportive Pharmaceuticals Dispensaries will ensure that all certifications are labeled properly.
B. Cross-contamination of product will be prevented by Kinex Supportive Pharmaceuticals Dispensaries.
C. Kinex Supportive Pharmaceuticals Dispensaries ensure that drugs are packaged in a way to maintain stability and usability for the patient.
D. Kinex Supportive Pharmaceuticals Dispensaries will appropriately dispense an emergency or interim supply of medication to prevent interruption of services based on emergencies or local disasters when appropriate.

Responsible Area:

Dispensary Operations

PROCEDURE:

A. During the final certification verification done by a Pharmacist, the entire certification is verified ensuring all labeling is appropriate and that all materials contained within the order match. The quantity displayed on the label is also verified by the Pharmacist before product dispensing. Auxiliary labels may also be used to denote special handling, storage, appearance, or administration of the medication to the patient.
B. Medications are packaged to ensure stability and usability by the time they reach the patient. Each medication order is dispensed and sent out of the pharmacy in a child proof bag in addition to the child proof container within.
C. An emergency or interim supply of medication may be necessary during a disaster or emergency. Pharmacists are available on an on-call basis to supply a medication in need to a person during a local weather event or emergency. The Pharmacist will work with the patient and verify when the next dose is actually needed by the patient to ensure there is no interruption of therapy. (NOTE This may not be allowed by NYS DOH but is normal quality care standard)

Dispensary Operations:
Product Handling, Storage, and Inventory

Sponsored By: Kinex Supportive Pharmaceuticals Dispensaries Team

POLICY:

A. Kinex Supportive Pharmaceuticals Dispensaries will verify that products are handled and stored appropriately based on temperature and storage requirements. Additionally, Kinex Supportive Pharmaceuticals Dispensaries ensure the accountability and security of the dispensary inventory.
B. Inventory will be managed to ensure that drugs are stable and usable.
C. Kinex Supportive Pharmaceuticals Dispensaries ensures that medication will be handled, stored, and disposed of appropriately and safely to help protect employees, patients, and consumers.
D. Inventory will be monitored in accordance with State laws and GAAP

PROCEDURE:

A. Medications are stored based on manufacturer recommendations for storage based on USP temperature guidelines for room temperature and refrigerated unless otherwise stated. The delivery ticket for each medication and the system is labeled for each drug on what the storage conditions are. When new medications are added into the software, appropriate temperature designations are added to the necessary input field so that it will show up on the delivery ticket. Additionally, per shipping, medications are handled from the will call fridge or bay solely based on temperature requirements to ensure proper handling. If refrigerated items are currently being packed, only refrigerated items will be placed on the cart and brought to the dispensing area; and the same is true for room temperature medications. A full inventory of medications is conducted weekly and discussed with the Pharmacist in Charge to make necessary adjustments, or with the supervisor of claims to ensure proper billing. Medications are stored within a locked dispensary department. The only people with keycard access to the dispensary department are licensed pharmacists. This is monitored and maintained by physical security, and the supervising pharmacist. The dispensary is closed whenever a pharmacist is not on site. This department is also alarmed for any entry, with video surveillance.

The building surrounding the dispensary department is alarmed with entry alarms as well as motion sensors.

B. In addition to the above mentioned, Kinex Supportive Pharmaceuticals Dispensaries utilizes temperature controlled refrigerators to ensure that the medication is being stored properly. If the refrigerator is out of temperature range for more than 30 minutes, an alert system will notify the supervising Pharmacist 24 hours a day that there may be a potential issue. Also, there is a backup generator to ensure proper storage and refrigeration of medications during inclement weather. Throughout the weekly inventory process, expiration dates on medications are regularly verified to make sure the product is within date. If not then the medication is quarantined appropriately.

C. Kinex Supportive Pharmaceuticals Dispensaries ensures that State laws are consistently followed when completing inventory.

Dispensary Operations:
Handling and Removal of Unacceptable Drugs

Sponsored By: Kinex Supportive Pharmaceutical Dispensaries Team

POLICY:

(a) Kinex Supportive Pharmaceutical Dispensaries will appropriately handle and remove medications based on the manufacturer notifications.
(b) Kinex Supportive Pharmaceutical Dispensaries will provide proper instruction to the involved staff on the appropriate measures to comply with handling or disposal of medications.
(c) Kinex Supportive Pharmaceutical Dispensaries will provide notification to consumers and providers when necessary on processing and handling the disposal of medications.
(d) Kinex Supportive Pharmaceutical Dispensaries will review and remove stocked inventory appropriately.
(e) Kinex Supportive Pharmaceutical Dispensaries will work to identify and remove inventory in the process of being filled or prior to filling when appropriate.
(f) Kinex Supportive Pharmaceutical Dispensaries ensure that all medications to be disposed of are done appropriately.

PROCEDURE:

A. Kinex Supportive Pharmaceutical Dispensaries will place medication that has been recalled, discontinued, expired, damaged, contaminated, or deemed unusable, in a separate part of the required USP temperature controlled, secure storage area until the product can be processed for return or disposal. Kinex Supportive Pharmaceutical Dispensaries monitor all medication recall notices for on-hand lots that may be affected.
B. All members of the dispensary staff are notified if a product that is supplied by Kinex Supportive Pharmaceuticals has been recalled so that lot numbers can be

monitored. This is performed through verbal communication, e-mail, or through departmental meetings.

C. If there is a patient level recall, patients can be notified by phone to check the lot number and expiration date of the drug that they have in hand. The manufacturer's recommendations on return, disposal, or replacement will then be followed.

D. Any recall that affects a product Kinex Supportive Pharmaceutical Dispensaries carries will lead to an overview of the medication to look for the lot number and/or expiration dates that have been affected. If found, the medication will be quarantined.

E. Any medication that has been recalled, discontinued, expired, damaged, contaminated, deemed unusable, is disposed of according to the manufacturer's recommendations and the safety and handling notices of the medication. Recalled medications are returned to the manufacturer per the recall notification. Discontinued medications are also returned to manufacturers per their guidelines. Expired medications are returned directly to the manufacturer based on their requirements. Damaged medications are disposed of based on the source of their damage. If received damaged, they are returned to the manufacturer. If they are damaged on site, or contaminated, or deemed unusable, they are disposed in accordance with the return policy of the manufacturer.

NOTE: The dispensary will always return using the security protocol developed in this plan. Under no circumstance will any other method be allowed.

Dispensary Operations:
Facility Safety and Security

Redacted pursuant to N.Y. Public Officers Law, Art.6

Section 8: Returns, Complaints, Adverse Events and Recalls

Kinex Supportive Pharmaceuticals will utilize the Recall Plan for our QuadPharma affilaiated company. The Recall plan has been approved by the FDA as meeting all requirements.

The plan is attached included here modifed with the Kinex Supportive company name.

Recall Procedure

1. PURPOSE:

   To describe the procedure for ensuring any individual or company using a product produced by the Kinex Supportive Pharmaceuticals, or any company using Kinex Supportive Pharmaceuticals ingredients that are subject to recall are identified and the recall process is successfully executed, including the proper notification to all affected parties.

2. RESPONSIBILITY:

   It is the responsibility of Quality Assurance (QA) Management to execute this procedure.

3. SAFETY:

   Refer to label of product.

4. MATERIALS/EQUIPMENT:

   N/A

5. DEFINITIONS:

   5.1. Drug Recall: The process by which information is shared to all affected and potentially affected parties that a product does not meet the standards as expressed in the label, or that the product has a defect that renders the product unsafe for consumption
   5.2. Customer: In the case of a cultivation center, a customer can be any individual or company in the entire supply chain.
   5.3. Supply Chain: The physical process that the products undertake from packaging (post manufacturing) to final use by the consumer. This includes

all forms of the product once packaged and labeled for sale
Inventory management system and tracking: A systematic process of organizing information to support the control of all “put ups” within the supply chain. The system will ensure 100% accountability of all inputs to the production of the end product and the disposition of those products to the final point of control within the supply chain. In the case of the Cultivation center, the control of the supply chain ends at delivery to the Dispensaries.

Notification: The process of informing customers that a product they possess or have use needs to be called and returned for testing and destruction.

5.5 “State Selected Software”: The software product that Kinex Supportive Pharmaceuticals is utilizing to implement and manage the inventory control requirements of the cultivation center license

6. ASSOCIATED FORMS:

6.1. Attachment 1: Label
6.2. Attachment 2: Communication log
6.3. Attachment 3: Disposition form

7. PROCEDURE:

QA Department or Designee

7.1. General rules:

7.1.1. Upon determination by QA and Compliance that a recall must be made, the recall notification plan must be commenced immediately. The plan should be completed in 72 hours or less. The time commences when all required complaint documentation is verified by QA. An effectiveness Assessment must be provided to the CEO and Chief Compliance officer every 24 hours, until the recall is considered complete.

7.1.2. Notifications taking longer than 3 calendar days to complete will require a rationale for the extended time and will be documented in the recall review final report.

7.1.3. The recall final report will be reviewed with all employees, and will be utilized for continuous process improvement.

7.2. Kinex Supportive Pharmaceuticals QA Department will maintain responsibility for the recall process throughout the recall.

7.3. Utilizing the inventory management tools within the Bio track inventory system, all sales orders and confirmed delivery tickets will be searched to

determine where any product with the recalled lot or batch numbers were sent.

7.4. Using the delivery ticket confirmation log, immediate first person communications will be made. These first person calls will be made to the individual dispensary emergency contact as provided and recorded in our management system. Where the number is a cell phone, a text message will also be sent.

7.5. The second communication method will be emails sent to the emergency contact person as identified by dispensary. In order to build redundancy in case of a failure by the dispensary to maintain an accurate contact database with Lange Group, a general email will also be sent to the dispensary's general email, where one exists.

7.6. In all cases, a certified letter sent via U.S. mail will back up the above communication methods

7.7. A determination will be made by the CEO based on information received from the Compliance officer as to whether a recall should be made using media sources. If there is any question that the Dispensary's have failed to manage the patient data properly, and cannot produce an accurate consumer contact list, a media based recall will be made.

7.8. Dispensary's will follow the states guidance on accepting returned goods, and will coordinate with the Cultivation center to arrange for return using secure means.

7.9. Patients will be provided replacement product at no cost to them, unless this violates any rules under the program.

This program will be administered without regard to cost. The primary goal of patient safety will always be maintained as the most important value driving our organization.

Item Recalled	**Lange Item/Lot Number**	**Phone called Log Date**	**Contact person**	**Date Notified**	**Date Sample(s) Received, if applicable, Quantity and Condition of Sample(s)**	**# of Containers / Samples Received**

Dispensary Communication Log/ Customer Number:_____

Investigation of Customer Complaints, Adverse Reactions

8. PURPOSE:

   To describe the procedure for the investigation of any cannabis product produced by Kinex Supportive Pharmaceuticals based on a Consumer's complaint, internal discovery or external lab reporting. This procedure is applicable to all products manufactured and/or packaged by Kinex Supportive Pharmaceuticals for its Customers.

9. RESPONSIBILITY:

   It is the responsibility of Quality Assurance (QA) Management to execute this procedure. Responsibility for on-going maintenance of program will reside with the Chief Compliance officer

10. SAFETY:

    Refer to label of product.

11. MATERIALS/EQUIPMENT:

    N/A

12. DEFINITIONS:

    12.1. Adverse Drug Event (ADE): Any adverse event associated with the use of a drug in humans, whether or not considered drug or medical device related, including the following: an adverse event occurring in the course of the use of a drug product or medical device in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

    12.2. Consumer: Initial source of complaint and sample. Could be an end user, pharmacist, care giver or other observer.

    12.3. Consumer Complaint: Any information received by Kinex Supportive Pharmaceuticals that alleges a possible concern regarding product quality, following the release of the product for distribution, or any information received that suggests a product has caused or contributed to an adverse drug event or injury.

    12.4. Customer: The organization that Kinex Supportive Pharmaceuticals is providing the complaint evaluation service for. Typically these are products manufactured by Kinex Supportive Pharmaceuticals and are commercially distributed through dispensaries.

    12.5. Initial Impact Assessment (IIA): A risk assessment that is conducted at the onset of the investigation to determine immediate impact on product in distribution or remaining within the company's inventory.

12.6. Risk Assessment: A systematic process of organizing information to support a risk decision. It consists of the comparison of the estimated risk using the following risk criteria:

12.6.1. Severity- A measure of the possible consequences of a hazard, impact on product SQIPP (Safety, Quality, Identity, Purity, Potency), manufactured lots, materials, equipment, and/or areas/systems.

12.6.2. Probability- The likelihood that a risk will occur.

12.6.3. Detectability- The ability to discover or determine the existence, presence, or fact of a hazard.

12.7. Overall Risk: The combination of the probability of occurrence of harm, the severity of that harm, and the detectability of that harm.

12.7.1. Major (High Impact)- A major impact assessment indicates there is an impact to product, lots, materials, equipment, and/or areas/systems.

12.7.2. Moderate (Probable Impact)- A moderate impact assessment indicates there is a potential impact to product, lots, materials, equipment, and/or areas/systems.

12.7.3. Minor (Minimal Impact)- A minor impact assessment indicates there is not likely to impact to product, lots, materials, equipment, and/or areas/systems.

13. ASSOCIATED FORMS:

13.1. Attachment 1: Consumer Complaint Log
13.2. Attachment 2: Consumer Complaint Sample Label
13.3. Attachment 3: Consumer Complaint Investigation Guidelines

14. PROCEDURE:

QA Department or Designee

14.1. General rules:

14.1.1. Complaint investigations shall be completed within 30 calendar days from date of notification of the complaint. Receipt date commences when all required complaint documentation is received at Kinex Supportive Pharmaceuticals from the complainant. An Initial Impact Assessment of the complaint shall be completed within 3 business days from date of notification of the complaint.

14.1.2. Investigations taking longer than 30 calendar days to complete will require a rationale for the extended time and will be documented in the Consumer Complaint Final Report.

14.1.3. A Consumer Complaint cannot be investigated without a legible Lot Number. In these cases a Final Report will be issued stating that the investigation could not be conducted because the Lot Number was not available.

14.2. Kinex Supportive Pharmaceuticals QA Department will receive product related Consumer complaints and samples, if available, from the consumer.

14.3. A Consumer Complaint Number will be issued from the Consumer Complaint Log (Attachment 1).

14.3.1. The Consumer Complaint Number will consist of the following:

Example: CCIXXX-0001

XXX = Customer Number
0001 = Sequential Number

14.3.2. The following information will be entered in the Consumer Complaint Log:

14.3.2.1. Complaint Number
14.3.2.2. Customer Number
14.3.2.3. Item/Lot Number
14.3.2.4. Complaint Received By/Date
14.3.2.5. Description of Complaint
14.3.2.6. Date Customer Notified, if required
14.3.2.7. Date Samples Received, if applicable, Quantity and Condition of Sample(s)
14.3.2.8. Disposition of Samples Upon Completion of Complaint

14.4. A Consumer Complaint Sample Label (Attachment 2) will be placed on each Consumer Complaint Sample received at Kinex Supportive Pharmaceuticals. The label will contain the following information:

14.4.1. Consumer Complaint Number
14.4.2. Product Name
14.4.3. Product Lot Number
14.4.4. Signature / Date

14.5. A Consumer Complaint Investigation will be completed for each complaint received (refer to Attachment 3 for Consumer Complaint Investigation Guidelines which can be used a template for the investigation). All information supplied by the consumer concerning the Consumer Complaint will be attached to the Consumer Complaint Investigation. Complete an Initial Impact Assessment (IIA) within 3 business days from notification of the complaint. Provide an initial risk assessment and an initial overall risk within the IIA. This risk assessment should be reviewed by Quality and Operations management as well as by the customer to assure the severity and scope of the complaint is well understood. The Consumer Complaint Investigation will contain the following information:

14.5.1. Based on the nature of the complaint, the customer and Kinex Supportive Pharmaceuticals will determine what investigative directives will be performed on the complaint sample and retainer sample if requested/warranted.

Kinex Supportive Pharmaceuticals will list these directives in the Consumer Complaint Investigation.

14.5.1.1. If testing is required, Complaint Sample and Retain Sample, if required, will be delivered to the QC Lab for testing. This delivery transaction of the Complaint Sample(s) will be documented in the

Consumer Complaint Log. If an outside laboratory is utilized Lange group will ensure logging is consistent with this policy

14.5.1.2. Upon completion of testing, QC will deliver all data to the QA Department for inclusion in the Consumer Complaint Investigation.

14.5.2. Include a review of manufacturing, packaging, and testing records for the complaint lot in the Consumer Complaint Investigation.

14.5.3. Document any conversations with personnel associated with a product's history of production, packaging, and testing within the Consumer Complaint Investigation.

14.5.4. Include Retain Sample Inspection Results, if required.

14.5.5. Include stability testing results for the complaint lot, if available.

14.5.6. Provide any complaint trending for the product or lot and the potential for impact to the product or manufacturing process.

14.5.7. Provide a final risk assessment and overall risk.

14.6. Obtain Operations Management and Quality Assurance Management approval upon completion of the Consumer Complaint Investigation.

14.7. Provide a copy of all completed complaint investigation records to the customer and file all documentation in Central File under the consumer complaint investigation file.

CONSUMER COMPLAINT LOG Customer Number:_____

Complaint Number	Lange Item/Lot Number	Complaint Logged By/Date	Brief Description of Complaint	Date Customer Notified QDP	Date Sample(s) Received, if applicable, Quantity and Condition of Sample(s)	# of Containers / Samples Received

QA Reviewed By:_____ Date:_____

Page Number: _____ Issued By: _____ Date: _____

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT SAMPLE

Consumer Complaint Number: ________________
Product Name: _____________________________
Product Lot Number: _________________________
Signature / Date: ____________________________

SOP 000-03-00-0027 Effective Date: 07/12/2012

CONSUMER COMPLAINT INVESTIGATION GUIDELINES

Consumer Complaint Number:_____
Customer Name/Number:_____
Date Complaint Received from Consumer:_____
Initial Impact Assessment Due Date: _____
Investigation Due Date:_____

This is a general guideline of contents:

1. *Describe the Consumer Complaint in detail based on information supplied by the Customer and any additional information provided by the customer.*

    1.1. List and attach all documents given to QDP by the Consumer concerning the Consumer Complaint.

2. *List all investigative directives requested by the consumer. Include the following information if required:*

    2.1. List all testing to be performed along with test method numbers and limits. Note if Retainer testing is also required.

    2.2. Review of Bulk BPR.

    2.3. Review of Packaging Document.

    2.4. Review of QC Certificate of Analysis (COA) for product release.

3. *List the results of all Investigation parameters:*

    3.1. List all testing results, test methods, and limits. Report any out of limit results to QC management.

    3.2. Discuss the findings for review of BPR, Packaging Document, and QC C of A .

    3.3. Discuss any new information gained from any conversations with personnel associated with a product's production, packaging, and original testing.

    3.4. Provide Retain Sample Inspection Results, if required.

    3.5. Provide Stability Testing Results, if available.

    3.6. Discuss any complaint trending noted for the product and lot and the potential for impact to product or manufacturing process..

    3.7. Provide a Risk Assessment and Overall Risk.

TRAINING REQUIRED:

- [x] Read Only Training
- [ ] Self-Study Training with Quiz (See Management)
- [ ] Technique Training (See Management)

REVISION HISTORY:

Version Number	Change Control Number	Current	Change To/ Justification	Effective Date
1	CC2012-0024	New Procedure	New Procedure	07/12/2012
2	CC2014-			

Written By:_____ Signature on File Date:_____
Department Head Approval:_____ Signature on File Date:_____
Quality Assurance Approval:_____ Signature on File Date:_____

Returned Goods

1. PURPOSE:

To define the method by which return goods will be processed at Kinex Supportive Pharmaceuticals.

2. RESPONSIBILITY:

2.1 Customer Service is responsible for customer interactions and will complete a Non-Conformance (Deviation) Report– NCR per SOP 1.275 for all product returns.
2.2 Customer Service is responsible for preparing and sending a Product Storage Affidavit (PSA) Form, Attachment A of this SOP to the customer.
2.3 If Return of Material is Authorized Customer Service will provide the Return Goods Authorization number (RGA) to the Customer, update the NCR with that information and complete the Request for Return Goods Section of the Returned Items - Inventory Data Sheet (RI-IDS), Attachment B of this SOP. Once complete, forward that document to Shipping/Receiving.
2.4 Quality Systems is responsible for review of Attachment A.
2.5 Quality Systems is responsible for review of Attachment B.
2.6 Shipping/Receiving is responsible for Receiving, Sampling, and Labeling Returned Items using Attachment B and labeling returned goods using Attachment C.
2.7 The MRB is responsible for evaluating Non-Conformance (Deviation) Reports, initiating investigations, and evaluating corrective action activities regarding returned goods.
2.8 The MRB is also responsible for final disposition of the returned goods.

3. SAFETY:

Refer to product label prior to handling any returned goods.

4. PROCEDURE:

4.1 Types of returns:
4.1.1 Authorized: Arranged with the advance knowledge of Kinex Supportive Pharmaceuticals.
4.1.1.1 An NCR has been generated by Customer Service.
4.1.1.2 Attachment A has been signed by the Customer and Quality Systems has approved the return of the product.
4.1.1.3 A Return Goods Authorization number (RGA) will be assigned by Customer Service.
4.1.1.4 Attachment B of this SOP will be prepared and used to manage the returned material.
4.1.2 Unauthorized: Product arrives without the advance knowledge Kinex Supportive Pharmaceuticals.

4.1.2.1 A RGA number has not yet been assigned and no NCR been created.
4.1.2.2 All unauthorized returns will be directed to Customer Service by sending the pack slip or other available information contained on the shipment.
4.1.2.3 Customer Service will begin the Returned Goods Process for Authorized Returns.

4.2 Return receipt procedure:
4.2.1 Customer Service will generate a Non-Conformance (Deviation) Report – NCR per SOP 1.275 for all customer requested product returns
4.2.2 Customer Service will prepare Attachment A and send it to the customer.
4.2.3 Once the signed Attachment A is received back from the Customer, Customer Service will forward that form to Quality Systems for review.
4.2.4 Quality Systems will then review the completed Attachment A and accept or reject the return of the product.
4.2.5 If rejected, Quality Systems will notify Customer Service that we will not allow the product to be returned.
4.2.6 If accepted, Quality Systems will forward Attachment A to Customer Service who will issue the customer an RGA number and allow the product to be returned to Kinex Supportive Pharmaceuticals.
4.2.7 Customer Service will then prepare Attachment B of this SOP and forward that form to Shipping and Receiving.
4.2.8 Shipping/Receiving will retain Attachment B until returned product is received.
4.2.9 Upon receipt of customer returned goods, Shipping/Receiving will complete the Receiving Section of Attachment B. Each package will then be labeled with Attachment C, Returned Goods Label. All product returns will be stored in the appropriate storage temperature.
4.2.10 Shipping/Receiving will complete the Receiving Section of the (RI-IDS) form, Attachment B of this SOP.
4.2.11 Shipping/Receiving will process a product return or a credit memo to return the product into the inventory system in the Warehouse on “In Inspection” status.
4.2.12 Shipping/Receiving designee will then update the NCR with Credit Memo Number issued, date, quantity and any other comments noted on Attachment B. *Example: 150g returned on (date) in good condition.* Employees will place their initials next to comments.
4.2.13 If <u>all</u> of the Packaging, Containers, Seals, and QDP label are in acceptable condition, Shipping/Receiving will proceed to Sampling Section of Attachment B and check No on the Sample Section, N/A number of containers sampled, sign and date the form and forward it to Quality Control for review.
4.2.14 If any of the Packaging, Container, Seal, or label is damaged or missing, Shipping/Receiving will proceed to Sampling Section of Attachment B and collect a 1 gram sample per SOP for Sampling, label each sample, sign, date and forward the sample and form to Quality Control for testing.

4.3 Quality Control procedure:

4.3.1 Quality Control will review and complete QC Testing Review Section of Attachment B.
4.3.2 If additional testing is required, Quality Control will request additional samples to be acquired by Shipping and Receiving by issuing a Special Test Request Form, WI-58.
4.3.3 Quality Control will forward the (RI-IDS) Form Attachment B of this SOP to Quality Systems.

4.4 Quality Systems procedure:
4.4.1 Quality Systems will search the NCR Database for other possible problems associated with the lot number of the returned product.
4.4.2 The decision to release or to discard product returns will be made by the Material Review Board (MRB) chaired by the Chief Compliance officer
4.4.3 The disposition of the returned material will be recorded in the Non-Conformance (Deviation) Report.
4.4.4 If MRB makes the decision to return the material as it is labeled to salable inventory, Quality Systems will transfer the returned goods to 01 or LF Warehouse on “On-Hand” status and forward Attachment B to Shipping/Receiving to complete Distribution Final Review.
4.4.5 If MRB makes the decision to discard the material, MRB will assign a designee to prepare a Product Discard Sheet, per SOP, Attachment B, Assessment of Expiration Date for Product, and forward that with Attachment B to diversion control personnel for processing.
4.4.6 Completed Attachment B and if applicable the Product Discard Sheet, Attachment B, SOP 1.400,will be returned to Quality Systems for filing.

Product Storage Affidavit from Customer

Responsibility: Kinex Supportive Pharmaceuticals Customer Service Department

The product listed below has been requested for return to Kinex Supportive Pharmaceuticals (QDP):

Item Code: _____ **Lot #**: _____

Customer Catalog Number: _____ **Customer Lot#:** _____
(if applicable)
Reason for return: _____

Date request received: _____**Qty. for return:** _____

RGA# assigned: _____ **By/Date:** _____

Responsibility: Customer requesting return
Customer Name and Addre

The labeled storage requirements for this material is storage at:
☐ **15ºC to 30ºC** ☐ **2ºC to 8ºC** ☐ **-10ºC to -25ºC**

Note: Your signature below indicates that the materials have been stored under these conditions while in your possession.

Customer signature: _____ Date: _____

Position: _____
(Note: Quality Management representative or Supply Chain /Distribution Management level signature required).

Return to Lange Compliance Office: Attention: Customer Service, Fax: 1-716-XXX-XXXX or scan and send to the respective Lange Group contact that you have been working with.

Responsibility: Kinex Supportive Pharmaceuticals Quality Systems Department

NCR#: _____

QS Final Review: **Accepted ☐** **Rejected ☐**

By: _____ Date: _____

NOTE:

Forward this document to Customer Service to Issue a Returned Goods Authorization to the Customer

Returned Items-Inventory Data Sheet

Catalog # _____ **Lot #** _____

Request for Return Goods: Responsibility: Customer Service
Reason for Return: _____
Customer Material Storage Affidavit: □ Sent to customer □Returned from customer □ Issue
Returned Goods Authorization RGA #: _____
NCR#: _____

Receiving: Responsibility: Distribution
RGA # _____Product Description: _____

_____

Customer: _____Received By/Date: _____

Quantity Received: _____Expiration Date: _____

Inspection:
Packaging ( ) Acceptable ( ) Damaged
Container ( ) Acceptable ( ) Damaged
Seal ( ) Acceptable ( ) Damaged Qty. Seal Intact: _____ Qty. Seal Not Intact: _____
Labeling ( ) Acceptable = QDP labeled material Label current: ☐ Yes ☐ No
( ) Unacceptable = Non-QDP labeled material
Comments/Other: _____
Quarantine/Final Storage Location _____

_____

Sampling: Responsibility: Distribution
Sample quantity for Identification testing required? ☐ Yes (proceed to sampling) ☐ No (forward to QC)
Sample quantity: _____Number of containers sampled: _____

Sampled By/Date: _____

Sent to QC By/Date: _____

QC Testing Review / Approval: Responsibility Quality Control
QC Checks: Specification version at the time of release = Effective date: _____
Specification version at the time of return = Effective date: _____
Additional testing required: ☐ Yes (testing updated) ☐ No (no testing updated)

Testing: ☐ Conforms ☐ Does not conform By/Date: _____

Quality System Review: Responsibility QA Designee

NCR# _____ Reviewed By/Date: _____
Lot conforms to release specifications: ☐ Yes ☐ No
Labeling conforms to release requirements: ☐ Yes ☐ No
QS Final Review: Approved: ☐ Rejected:☐ Re-grade:☐ By/Date: _____
Transferred in Inventory System By/Date: _____

Supply Chain Review: Responsibility Supply Chain

The Catalog Number returned to QDP listed above has been re-assigned to Catalog#: _____
Labeling to by updated: Issued new Packaging and Labeling ☐ Yes ☐ No
By/Date: _____

Distribution Final Review: Responsibility Distribution

Product Stored at: ☐15-30°C,☐ 2-8°C, ☐ -10-25°C Product Discarded ☐
Quantity Stored: _____ Returned Goods Label removed: ☐ Yes ☐ No
By/Date: _____

Returned Goods
DO NOT
USE

Catalog # _____ LOT # _____

Product Description:

RGA # _____ NCR # _____

Comments:

_____

_____

_____

_____

_____

TRAINING REQUIRED:

- [x] Read Only Training
- [ ] Self-Study Training with Quiz (See Management)
- [ ] Technique Training (See Management)

REVISION HISTORY:

Version Number	Change Control Number	Current	Change To/ Justification	Effective Date
1	CC2014-	New Procedure	New Procedure	

Written By:_____Date: _____

Department Head Approval:_____Date: _____

Quality Assurance Approval:_____Date: _____

"State Selected Software's batch tracking functionality allows for easy traceability of any batch in the system. With "State Selected Software's custom reporting utility, batches of medical marijuana can be traced back to their original source and tracked to every customer that received marijuana from any batch in question. Sales transactions are tied to customer records and are easily traceable to their original source, as well as to the totals for the time period in question. Transactions can be reloaded into the software at any time so that the transaction log and order details can be reviewed. Reporting functionality also allows a batch to be traced back to its harvest, and all plants included in that harvest, in order to examine any processes carried out with the cultivation or post-harvest process relevant to a batch in question.

8.1 Complaint files

(a) Manufacturing, packaging, labeling, and holding operations will establish written procedures describing the handling of product complaints received regarding a marijuana-derived product.

(b) A qualified person will:

(1) Review product complaints to determine whether the product complaint involves a possible failure of a product to meet any of its specifications, or any other requirements, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury; and

(2) Investigate any product complaint that involves a possible failure of a product to meet any of its specifications, or any other requirements of this part, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury.

(c) The Quality Control Officer will review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed.

(d) The review and investigation of the product complaint, and the review by the Quality Control Officer about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, will extend to all related batches and relevant records. Related batches may include, but are not limited to, batches of the same product, other batches processed on the same equipment or during the same time period, or other batches produced using the same batches or lots of components or packaging components.

(e) A written record of the complaint and where applicable its investigation will be kept, including:

(1) Identity of the product;

(2) Batch, lot or other control number of the product;

(3) Date the complaint was received and the name, address, or telephone number of the complainant, if available;

(4) Nature of the complaint including, if known, how the product was used

(5) Names of personnel who do the following:

(i) Review and approve the decision about whether to investigate a product complaint;

(ii) Investigate the complaint, and

(iii) Review and approve the findings and follow-up action of any investigation performed.

(6) Findings of the investigation and follow-up action taken when an investigation is performed; and

(7) Response to the complainant, if applicable.

(f) Manufacturing, packaging, labeling, and holding operations will establish a procedure for a product complaint that includes a report of an adverse event. For purposes of this section, an adverse event is a health-related event associated with use of a product that is undesirable, and that is unexpected or unusual. The procedure will address whether the adverse event requires the following:

(1) Reporting to any public health authority;

(2) Reporting to the physician of record for the individual reported to have experienced the adverse event, if known; and

(3) Product recall.

8.2 Returned products

(a) Manufacturing, packaging, and/or labeling operations will establish written procedures describing the receipt, handling, and disposition of returned marijuana-derived products.

(b) Returned products will be identified as such and be quarantined upon receipt.

(c) Returned product will be reviewed and approved or rejected by the Quality Control Officer.

(d) If the conditions under which returned product has been held, stored, or shipped before or during

its return, or if the condition of the product, its containers, or labeling, as a result of storage or shipping, casts doubt on the identity, purity, strength, composition, or freedom from contamination or adulteration of the product, the returned product shall be rejected unless examination, testing, or other investigations prove the product meets appropriate standards of identity, purity, strength, and composition and its freedom from contamination or adulteration.

(e) If the reason a product is returned implicates associated batches, an appropriate investigation will be conducted and will extend to all related batches and relevant records. Related batches may include, but are not limited to, batches of the same product, other batches processed on the same equipment or during the same time period, or other batches produced using the same components or packaging components.

(f) Rejected returned product returned to the manufacturing, packaging, labeling, and holding operation will be destroyed.

(g) A written record will be kept of the return, and where applicable its investigation, including:

(1) Identity of the product;

(2) Batch, lot or other control number of the product;

(3) Date the returned product was received;

(4) Name and address from which it was returned, and the means by which it was returned;

(5) Reason for the return;

(6) Results of any tests or examinations conducted on the returned product, or on related batches, if any;

(7) Findings of the investigation and follow-up action taken when an investigation is performed;

(8) Any reprocessing performed on the returned product;

(9) The ultimate disposition of the returned product, and the date of disposition; and

(10) Names of the Quality Control Officer who do the following:

(i) Review the reason for the product return;

(ii) Review and approve any reprocessing, as applicable, and

(iii) Review and approve the findings and follow-up action of any investigation performed.

8.3 Recall procedures

(a) Manufacturing, packaging, labeling, and holding operations will establish a procedure for

recalling a product that has been shown to present a reasonable or remote probability that the use of the product will cause serious adverse health consequences or could cause temporary or medically reversible adverse health consequences. This procedure will include:

(1) Factors which necessitate a recall;

(2) Personnel responsible for a recall; and

(3) Notification protocols.

(b) Manufacturing, packaging, labeling, and holding operations will establish a procedure for communicating a recall of product distributed by the operation. This procedure will include:

(1) A mechanism to contact all customers that have, or could have, obtained the product from the operation;

(2) A mechanism to contact the vendor that supplied the recalled product to the operation, if applicable;

(3) Instructions for the return or destruction of any recalled product by customers;

(4) Instructions for contacting the relevant manufacturing, packaging, labeling, and/or holding operations; and

(5) Communication and outreach via media, as necessary and appropriate.

Section 9: Product Quality Assurance

9.1 Sanitation Plan Overview

Plant Description and Background:

The company will produce botanical based pharmaceutical products utilizing natural and processed raw material/products that contains known biologically-active compounds which when in defined quantitative and qualitative amounts provides a documented health benefit, and thus, an important source in the prevention, management and treatment of chronic diseases of the modern age. The Company will produce these pharmaceuticals under strict adherence to sanitation protocols to assure quality assurance and quality control of all raw ingredients and finished products.

The format of this sanitation plan is based on the USDA/FSIS/FDA templates traditionally used in this country. We utilized the approved BSI risk assessment model to determine the significance of our hazards. This plan follows the traditional Management System of Codex Alimentarius and the guidance document of NACMCF for the Development of sanitation Plans.

Prerequisite programs and activities:

Before implementing this sanitation plan, the following plant-wide programs and activities were evaluated and maintained. The plant conducts routine audits of the prerequisite programs. Programs include but are ***NOT*** limited to

- Current diagram of layout indicating product flow (blueprint diagram);
- The Company's Supplier Specification (certification) Requirements;
- Cleaning and sanitizing procedures, including SSOP's;
- Preventive maintenance documentation for equipment, including calibration;
- Training programs;
- Procedures for receiving and storing ingredients;
- Recall procedures including, traceability of raw materials to suppliers, coding of finished product, traceability through distribution and periodic mock recalls to verify that it works in the event of an actual recall;
- Supplier audit program (e.g., review of supplier sanitation plans, purchase specifications, and letters of guarantee).

These programs are the foundation on which the sanitation plan was developed and are important to the reliable functioning of the sanitation plan. The procedures for these programs are outside the scope of the sanitation plan.

Company commitment:

We are proud of the products we produce and are committed to producing the highest quality and safest product in the industry. When developing theses sanitation plans, raw material/products safety is our primary concern. The sanitation concept deals with raw material/products safety and every effort has been made to evaluate all such hazards.

Sanitation Team members:

Our sanitation Team members include people from all segments of production and administration. They are:

1. Quality Assurance Officer
2. Extraction & Infusion Scientist

Training and sanitation Team Meetings:

The sanitation coordinator will attend a class on the Development and Implementation of sanitation, which is accredited by the International sanitation Alliance, Texas A &M University, located in College Station Texas.

Monitoring training for Critical Control Points and on-going training will be conducted.

Sanitation team meetings (monthly) and re-assessment meetings (annually) are held and documented.

Process categories:

All products are produced under one process categories. It is:

I. Sub-lingual sprays

Documentation with specific ingredients is proprietary and available on request.
Flow charts were developed for all processes. A Master Hazard Analysis was developed for all processes found on the flow charts.

Control Points:
Control points for process control are incorporated into the plants GMP'S and SOP'S

Critical Control Points:
Critical control points are specified in the sanitation plan.

9.2 Personal Hygiene

9.2.1 Employee Personal Hygiene Policies:

Employees shall be responsible for using safe handling methods as trained and instructed, and for practicing good personal hygiene.

The following are the policies for every employee to follow to eliminate raw material/products borne illness and injury, and to achieve certainty in customer satisfaction.

9.2.2 Individual illness and disease control:

Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesions (boils, sores, infected wounds) or any abnormal source of microbial contamination that could contaminate raw material/products, raw material/products contact surfaces, or raw material/products packaging materials shall not be allowed to work with these items.

If an employee's illness is not severe and symptoms are not acute, the employee can be assigned to tasks that do not involve handling or can be excused from work altogether until he/she is completely well. Illness will not be passed on to customers or other employees.

Employees, notify your supervisor / PIC if you are ill with diarrhea, vomiting, or other illness so that you can either be assigned to tasks that do not involve raw material/products handling, or excused from work altogether.

When employees are hired, they will be taught to tell the supervisor / PIC if they have:

a. Diarrhea or vomiting.

b. Salmonella, Shigella, E. coli O157:H7, hepatitis A, or other intestinal illness (diagnosed by a doctor).

c. Open, blistered, or infected burns, boils, cuts, etc. on the hands or forearms.

d. Burns, wounds, or boils on the hands or forearms that are open, blistered, or have pus.

e. Jaundice (yellowing of the skin or eyeballs).

What to do when an employee has:

a. Diarrhea or vomiting.
    i. Do not allow employees to work until they are well.

ii. Keep a written record of all employee reports of diarrhea and vomiting. A sample log page is included in this manual.

b. Hepatitis A. Salmonella, Shigella, E. coli O157:H7, other intestinal illness.
   i. Call your local health department to report the illness.

   ii. Do not allow employees with diarrhea or vomiting to work until they are well.

   iii. Employees without diarrhea or vomiting can work, but not with raw material/products or raw material/products-contact surfaces (clean equipment, utensils, linens, and single-service and single-use items).

c. Open, blistered, or infected burns, boils, cuts, etc. on the hands or forearms.

   i. Supply the employee with a waterproof bandage to apply to the boil or wound.
   ii. Supply gloves, which will be worn it the boil or wound is on the hand or wrist.

d. Persistent sneezing, coughing, or a runny nose.
   i. People with these symptoms can work, but will not work with raw material/products.

e. Cuts and abrasions:
   i. Clean all cuts and abrasions using soap and disinfectant, water, and a brush. There is no need to put a glove on the other hand if it has no problems. When the uncovered hand gets dirty, it will be a signal to the worker to change gloves and continue to wash his or her hands. Bacteria will grow on the warm, moist skin under the glove, so take the glove off, wash hands and put on a fresh glove frequently. Never handle raw material/products with an infected cut or abrasion. (See also FIRST AID in this section.)

9.3 Personal Cleanliness

a) Maintain adequate personal cleanliness by bathing daily and using a deodorant to control body odor. Use only mild perfumes or colognes that do not interfere with the aroma of raw material/products. Keep hands free of foreign perfume odors.

b) Wear clean uniforms and closed-toed shoes. Replace clothing if it becomes dirty while working.

c) Store clothing and personal belongings away from raw material/products production or equipment / utensils washing areas.

i. Fingernails. Keep fingernails neatly trimmed. Fingernails will not protrude past the ends of the fingertips more than 1/16" in length to make them easier to clean.

ii. Do not use fingernail polish or artificial fingernails while working, because they might flake or fall off into a customer's raw material/products.

iii. Hair restraint. Restrain or cover your hair at all times (e.g., hairnets, headbands, caps, beard covers). The covering or restraint will ensure that no hair will fall into the customer's raw material/products. Employees with mustaches and beards keep facial hair clean, neat, and trimmed.

iv. Mustaches cannot extend below the lip. Beards will be kept closely trimmed to no more than 1/2 inch. A beard net will be worn at all times in the processing area.

v. Jewelry and hard objects in pockets. Do not wear jewelry on the hands, wrist, neck, or ears.

vi. Do not carry hard objects in your outside pockets.

vii. Plain wedding bands are acceptable but not recommended.

viii. Handkerchiefs and facial tissues. Never carry a handkerchief or facial tissue when working with raw material/products. If you will use a tissue, use it at the hand sink, then immediately wash your hands at the hand sink. If you sneeze, direct it toward your shoulder and away from raw material/products.

ix. Chewing gum, smoking, and eating. Do not chew gum when working with raw material/products.

x. Never smoke in the raw material/products production area.

xi. Never eat or drink while handling raw material/products.

xii. Raw material/products and beverages are only consumed in the employee break room.

d) Toilet facilities are provided off the worker's dressing room, physically separated from processing areas. Toilet facilities have self-closing doors, are maintained in good repair, and are cleaned and sanitized daily at the end of the shift.

e) Hand washing facilities are provided in processing areas including the extraction lab and in the toilet facility. Hand washing facilities have: hot and cold running water with liquid sanitizing hand soap; hand sanitizer solutions; sanitary towel service; Signs directing workers to wash their hands and gloves thoroughly and sanitize them before starting work, after each absence

from their workstation, and anytime they have become soiled or contaminated; and refuse receptacles.

9.4 MEDICATION

Employees' personal medicines are stored in the plant manager's office, in case an employee will take personal medicine immediately.

9.5 FIRST AID

First aid materials are stored so that these materials cannot contaminate raw material/products.

a. First aid supplies shall be checked weekly by the PICs and shall be replenished.

b. Hand cuts and abrasions.

c. Employees will inform supervisors of cuts and abrasions on the hands and any other skin abrasions on exposed areas of the body.

d. Employees shall not work with any uncovered, ungloved infected cut or abrasion on the hands.

e. Cuts and abrasions that are not severely infected and do not interfere with an employee's ability to perform tasks shall be cleaned, disinfected, bandaged, and covered with a clean, waterproof covering (e.g. a clean, plastic glove) at the entrance to the plant.

f. After putting on glove, wash your ungloved hand.

g. You will need to use your gloved hand in the process of doing this.

h. Contact with blood or body fluids from another person.

i. Before any personnel touch the blood (e.g., if bandaging the wound of another individual) or any other body fluid such as vomitus of another person, they shall put on properly fitting, disposable gloves that will prevent the body fluid from entering any cuts or breaks in the skin of their own hands.

9.6 Water Safety

9.6.1 Control Measures

All water used in the plant is from a reliable municipal water system. The water system in the plant will be designed and installed by a licensed plumbing contractor, and meets current community building codes. All modifications to the plumbing system will be completed by a licensed plumbing contractor and will be inspected to ensure conformance with local building codes. All hoses inside and outside the plant have anti-siphoning devices installed. Floors are sloped to facilitate drainage.

9.6.2 Monitoring Procedures

The municipal water district routinely monitors the water to ensure that it meets state and federal water quality standards. The quality assurance supervisor receives and reviews annual reports of municipal water quality.

Twice a year, and when modifications are made to the plumbing system, water samples from at least four locations in the plant are sent to a private testing laboratory and examined for the presence of coliforms. Cultures testing positive for coliforms are examined for the presence of fecal coliforms. The quality assurance supervisor receives and reviews the laboratory reports.

9.6.3 Corrective Actions

In the event of municipal water treatment failure, the plant will stop production, determine when the failure occurred, and embargo all products produced during the failure until product safety can be assured. Production will resume only when water meets state and federal water quality standards.

If in-plant sampling indicates the presence of coliforms in more than 5% of plant water samples, the plant will contact the municipal water system and inspect the plumbing system to determine the source of the coliforms. Corrections will be made to the plumbing system, if necessary, to correct problems.

If in-plant sampling indicates the presence of fecal coliforms in any plant water sample, the plant will stop production and embargo all products until product safety can be assured. The plant will contact the municipal water system and inspect the plumbing system to determine the source of the fecal coliforms. Corrections will be made to the plumbing system, if necessary, to correct problems. Production will resume only when water meets state and federal water quality standards.

Floors with standing water will have the drains unplugged, or, if necessary, consultations will be held with plumbing or general contractors and corrections will be made to correct floor drainage problems.

9.6.4 Record Keeping

Reports are kept for municipal water quality, in-plant water quality testing, and corrective actions. Hose inspections, floor drainage inspections, and corrective actions are recorded on the Daily sanitation Report.

9.7 Facility, Equipment Cleaning, Sanitation & Pest Control

9.7.1 SUBSTANCES USED IN CLEANING AND SANITIZING; STORAGE OF TOXIC MATERIALS

a. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms.

b. Cleaning compounds and sanitizing agents shall be safe and adequate, as verified by any effective means, including purchase under a supplier's guarantee or certification, or examination for contamination.

c. Sanitizing agents shall be adequate and safe under conditions of use. Only the following materials are used or stored in the plant where product is processed or exposed:
   i. Those required to maintain clean and sanitary conditions.

   ii. Those needed for used in laboratory testing procedures.

   iii. Those needed for plant and equipment maintenance and operation.

   iv. Those needed for use in plant operations.

d. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored so as to protect against contamination of raw material/products, raw material/products contact surfaces, or raw material/products packaging materials. These materials shall be stored in locked and labeled facilities away from production or handling areas. Raw material/products-grade chemicals and lubricants are stored separately from non-raw material/products-grade chemicals and lubricants.

9.7.2 CLEANING & SANITIZING GMP'S

a. Preoperational sanitation. All equipment will be cleaned and sanitized prior to starting production. Sanitizer concentration will be measured and documented at least once daily. If sanitizer buckets are used for wipes or utensils, the concentration will be checked and recorded at least every 4 hours during production. Approved test strips recommended by the chemical supplier will be used to determine the strength of the solution that is used prior to sanitation. There will be a daily sanitation inspection of production lines before operations begin. This will be recorded on the Cleaning and Sanitizing Schedule and Pre-Operations Report.

b. Cleaning and sanitizing of utensils and equipment shall be conducted so as to protect against contamination of raw material/products, raw material/products contact surfaces, or raw material/products packaging materials. Raw material/products contact surfaces will be cleaned following contact with allergen-containing raw material/products. If high temperature sanitization is used instead of chemical sanitization, water temperatures will be measured and recorded for each cleaning cycle.

1) A written cleaning and sanitation program for all equipment and premises (production and storage areas) will be followed. (See Cleaning and Sanitizing Schedule and Pre-Operations Report) The program includes: the name of the responsible person; the frequency of the activity; the procedures for cleaning and sanitizing; the chemicals and concentrations used; the temperature requirements; and the type and frequency of inspection to verify the effectiveness of the program.

i. Sanitary procedures for cleaning and sanitizing equipment are used.
   i) The equipment is disassembled. Parts are placed in designated washing tubs, racks, and sinks.

   ii) Product debris is removed.

   iii) Equipment parts are rinsed with potable water

   iv) Equipment is sanitized with approved sanitizer, and rinsed with potable water if required.

   v) *Equipment is reassembled. (See sanitation Procedures and Standards)*

ii. Chemicals will be used in accordance with the manufacturer's instructions.

iii. The sanitation program will be carried out in a manner that does not contaminate raw material/products or packaging materials during or following cleaning and sanitizing (e.g. aerosols, chemical residues).

iv. Implementing, monitoring, and record keeping. The Quality Control Officer performs daily visual sanitation inspection after preoperational equipment cleaning and sanitizing. The results of the inspection are recorded on the Cleaning and Sanitizing Schedule and Pre-Operations Report. If everything is acceptable, the appropriate box is initialed. If corrective actions are needed, such actions are documented on the report.
   i) NOTE: **Operations will begin only after sanitation requirements are met.**

v. Corrective action will be taken, based on visual inspection of equipment and premises. Evidence of improper cleaning is, but not limited to: raw material/products particles, grease build-up (either yellow gummy or carbon), soap or water residue on surfaces, mold, dust, and oxidation of metals. The Quality Control Officer will mark type and area of concern on the checklist. This information will then be given to the person assigned to clean. Once the cleaning is completed, the QC person will re-inspect and make notation on the Cleaning and Sanitizing Schedule and Pre-Operations Report, of time cleaning was completed.

9.8 Sanitation of Raw Material/Products Contact Surfaces.

Cleaning and sanitizing of utensils and equipment shall be conducted so as to protect against contamination of raw material/products, raw material/products contact surfaces, or raw material/products packaging materials.

a. All raw material/products contact surfaces, including utensils and raw material/products contact surfaces of equipment, will be cleaned and sanitized as frequently as necessary to protect against contamination of raw material/products.

b. Raw material/products contact surfaces used for manufacturing or cleaning and sanitizing Schedule and Pre- Operations Report, Encl. B1.holding low-moisture raw material/products shall be in a dry, sanitary condition at the time of use.

c. When surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

d. Cleaning in wet processing: When cleaning is necessary to protect against introduction of microorganisms, all raw material/products contact surfaces shall be cleaned and sanitized before use and after any interruption during which the raw material/products contact surfaces may have become contaminated. Written procedures are in place for pre-operational inspection, cleaning during a production shift and post operational cleaning.
    i. Cleaning during continuous production: Where equipment and utensils are used in a continuous production operation, the utensils and equipment raw material/products contact surfaces shall be cleaned and sanitized as necessary.

    ii. Non-raw material/products-contact surfaces of equipment will be cleaned as frequently as necessary to protect against contamination of raw material/products.

    iii. Any facility, procedure, or machine shall be acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine routinely render equipment and utensils clean and provide an adequate cleaning and sanitizing treatment.

iv. Employees change outer garments, wash hands and sanitize hands with an approved hand sanitizer (sanitizer is equivalent to 50 ppm chlorine), put on clean gloves and step into a boot sanitizing bath on leaving and entering new rooms.

v. Corrective action. When the Quality Control Officer identifies sanitation problem(s) during production, the Processing Manager is notified and production is stopped. Employees are notified to take appropriate action to correct the sanitation problem(s). Employees are retrained, if necessary. Corrective actions are recorded on the Corrective Action Report.

9.8.1 Frequency of cleaning

a. Clean-ups of manufacturing and process equipment including stainless work tables, and floors in preparation room(s) will done once every 4 hours, as well as at the end of the production day.

b. Smaller utensils and equipment such as scales, thermometers, agriculture and manufacturing utensils will be cleaned after each use, in the 3- compartment sink wash-rinse-sanitize or in a utensil washing machine. Scales, racks for trays, and garbage cans will be cleaned on a daily basis at the completion of production shifts, or more often if necessary.

9.9 Storage of cleaned and sanitized portable equipment

Portable equipment with raw material/products contact surfaces and utensils shall be stored in a location and manner that protects raw material/products contact surfaces from contamination.

9.9.1 Cleaning of equipment

All equipment that has not be used, washed, and sanitized within the previous 24 hours will be re- washed and sanitized prior to placing into service. Before these pieces are placed back into circulation, QC will re-inspect.

9.9.2 Cleaning of facilities (includes floors, walls, and ceilings)

a) Separate cleaning equipment will be used for cleaning floors and walls and for equipment cleaning. All cleaning tools will be washed, rinsed, and sanitized, to include hoses, which are no more than 45 feet long.

b) Cleaning procedure
   i. Debris is swept up and discarded.
   ii. Facilities are rinsed with potable water
   iii. Facilities are cleaned with an approved cleaner, according to manufacturer's directions.

iv. Facilities are rinsed with potable water
v. Cleaning frequency

c) Floors and walls are cleaned at the end of each production day.

d) Ceilings are cleaned as needed, but at least once a year.
   i. Monitoring. The Quality Control Officer performs daily visual inspection prior to the start of operations.

   ii. Corrective action(s). When the Quality Control Officer determines that the facilities do not pass visual inspection, the cleaning procedure and re-inspection are repeated. The cleaning of facilities is monitored and sanitation crew is retrained if necessary. Corrective actions to prevent direct product contamination or adulteration are recorded.

9.9.3 Approved Chemicals list and Material Safety Data Sheets are on file.

a) Detailed information about all chemicals used in cleaning and employees will maintain sanitizing on file for easy access. This form is also used for pest control chemicals.

9.9.4 Reporting
a) Daily sanitation Reports are completed as records for compliance.

9.10 PEST CONTROL GMPs

GENERAL
a) There is removal of litter, waste, and cutting grass and weeds within the immediate vicinity of the buildings / structures to prevent breeding / harborage of pests.

b) There is inspection of the plant and extermination or other means to exclude pests, dirt, and filth that could contaminate raw material/products if neighboring grounds are not under the operator's control, and are not maintained as above.

c) No pets shall be allowed in any area of the raw material/products plant. Guard or guide dogs shall only be allowed in some areas where the presence of the dogs is unlikely to contaminate raw material/products; raw material/products contact surfaces, or raw material/products packaging materials.
d) Effective measures to exclude pests from processing areas and to protect against raw material/products contamination on the premises shall be taken.

e) Use of insecticides or rodenticides shall be used as defined by law and permitted only under precautions and restrictions that will protect against contamination of raw

material/products; raw material/products contact surfaces, and raw material/products packaging materials.

f) Documentation as part of a pest control program shall be maintained.

9.10.1 PEST CONTROL PROGRAM

a) A systematic pest control program is essential to prevent adulteration. If the facility is dirty no amount of pest control chemicals will prevent or stop insect and rodent infestation.
   i. The entire production facility is inspected regularly for any evidence of pests.

   ii. Storage areas are kept clean and free of debris and spilled raw material/products, which serve as a breeding area for pests.

   iii. Doors, windows, screens, walls, and floors are clean and well maintained so that pests cannot find a way into the establishment.

b) The use of properly cleaned and sanitized insect- and rodent-proof, covered trash containers discourages pest breeding. Floor drains are properly trapped to prevent insect and rodent entry.

c) All raw material/products items will be kept in closed, labeled containers and carefully inspected as received for evidence of pests before they are stored. Fresh ingredients are not added to old ingredients.

d) If pests are discovered, immediate steps are taken to eliminate them.

e) Sanitation requires verification by a supervisor or higher- level person that service provided by a pest control company was performed fully. This is done when the sanitation team does a monthly inspection of the facility.

f) Pest control reports are normally kept for six months.

g) Material Safety Data Sheets are kept and available for all pesticides used on the premises.

h) If traps are used to trap rodents, a Floor Plan will be made that indicates the location of these devices and the type of bait in each trap.

i) Pesticides will be used correctly. Any commercial chemicals used for pest control are toxic when not used correctly. A pest control chemical list will be maintained.

j) All raw material/products supplies will be placed in covered containers or removed from the area during pesticide application. All raw material/products contact surfaces will be covered or washed, rinsed, and sanitized after pesticide application.

k) Gaps around doors will be 1/4 inch or less.

l) All vendors will operate an effective pest control program. Service for outdoor poison bait will be monthly (licensed PCO only) and twice monthly for indoor rodent catch traps. Fly lights will be inspected and cleaned weekly.

m) Records will include a current business license from the pest control company, a certificate of liability insurance from pest control company, service records that specify the date of service, the nature of the service, and any observations or corrective actions that are necessary, an activity log for all devices, and a current device map with numbered locations and a legend that includes mechanical rodent traps, toxic bait stations, and insect lights. All toxic bait stations will be anchored to the ground and tamper proof.

n) A. chemical application log will be kept by the pest control service technician, and MSDS for all chemicals.

o) All outdoor toxic bait stations will be anchored to the ground, tamper resistant, numbered, and located at least every 50 linear feet around the building.

p) Indoor mechanical crawling pest devices will be numbered and located every 25 to 30 linear feet, along all indoor raw material/products storage areas.

q) Flytraps are placed as necessary, but not in direct view from outdoors so they do not attract pests from outdoors. Explosive devices will not be located in raw material/products production areas and will be at least 20 feet from stored raw material/products or packaging. Non-explosive fly lights will not be located above exposed raw material/products, but can be located within 10 feet.

9.11 FDA/ORA COMPLIANCE POLICY GUIDE

CHAPTER - 5 SUB CHAPTER - 555

SECTION 555.425 -Raw material/products - Adulteration Involving Hard or Sharp Foreign Objects

BACKGROUND:

Hard or sharp foreign objects in raw material/products may cause traumatic injury including laceration and perforation of tissues of the mouth, tongue, throat, stomach and intestine as well as damage to the

teeth and gums. From 1972 through 1997, the FDA Health Hazard Evaluation Board evaluated approximately 190 cases of hard or sharp foreign objects in raw material/products. These include cases of both injury and non-injury reported to FDA. The Board found that foreign objects that are less than 7 mm, maximum dimension, rarely cause trauma or serious injury except in special risk groups such as infants, surgery patients, and the elderly. The scientific and clinical literature supports this conclusion.

Hard or sharp natural components of a raw material/products are unlikely to cause injury because of awareness on the part of the consumer that the component is a natural and intrinsic component of a particular product. The exception occurs when the raw material/products label represents that the hard or sharp component has been removed from the raw material/products. The presence of the naturally occurring hard or sharp object in those situations (e.g., pit fragments in pitted olives) is unexpected and may cause injury. FDA has established Defect Action Levels for many of these types of unavoidable defects in other Compliance Policy Guides and therefore they are not subject to the guidance in this document.

REGULATORY ACTION GUIDANCE:
The following represent the criteria for direct reference seizure to the Division of Compliance Management and Operations (HFC-210) and direct reference import detention to the districts.

a. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm, in length.

and

b. Samples found to contain foreign objects that meet criteria a. and b., above will be considered adulterated within the meaning of 21 U.S.C. 342(a)(1). The following represent the criteria for recommending legal action to CFSAN Office of Field Programs, Division of Enforcement and Programs (HFS-605).

c. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm in length, and the product requires additional preparation or processing that may have an effect on the presence of the foreign objects in the finished raw material/products. For example, additional sifting of a product may or may not remove foreign objects, depending on the measurements of the objects and the mesh aperture of the sifter. In these situations, the preparation or processing of the raw material/products will be described in the recommendation submitted by the District.

or

d. The product contains a hard or sharp foreign object less than 7 mm in length and if a special-risk group, as defined in the background section, is among the intended consumers of the product.

or

e. The product contains a hard or sharp foreign object over 25 mm in length.

A sample found to contain a foreign object that meets criterion c., d., or e., above will be considered adulterated within the meaning of 21 U.S.C. 342(a)(1) if a health hazard is established by CFSAN review. The CFSAN health hazard review in this case will consider various factors including the intended use of the product, subsequent processing steps, official guidance and requirements concerning unavoidable natural defects, and other mitigating factors that could eliminate, invalidate or neutralize the hazard prior to consumption of the raw material/products product.

REMARKS:
If CFSAN review finds no health hazard associated with a sample containing a hard or sharp foreign object that meets criterion c., or d., above, the sample will be considered adulterated within the meaning of U.S.C. 342(a)(3) if a CFSAN review finds the article unfit for raw material/products. The CFSAN review in this case will consider various factors including subsequent processing steps, extent of contamination, and intended use of the product.

CPG 515.350 addresses imbedded objects in confectionary, which may cause such raw material/products to be adulterated within the meaning of 21 U.S.C. 324(d) (1).

SPECIMEN CHARGES:
The following charges are appropriate for a product that satisfies criteria a. and b. for direct reference seizure:

Article (was adulterated when introduced into and while in interstate commerce) (is adulterated while held for sale after shipment in interstate commerce), within the meaning of 21 U.S.C. 342 (a) (1), in that it bears or contains a deleterious substance which may render the raw material/products injurious to health.

Article is subject to refusal of admission pursuant to Section 801(a) (3) in that the article appears to bear or contain a deleterious substance, which may render it injurious to health.

9.12 Controlling Time and Temperature during the Extraction Process

PURPOSE: To ensure optimal control of extraction and processing variables.

SCOPE: This procedure applies to raw material/products service employees who prepare extracted

products.

INSTRUCTIONS:

1. Train raw material/products service employees on using the procedures in this SOP. Refer to the Using and Calibrating Thermometers SOP.

2. Follow State or local health department requirements.

3. Wash hands prior to preparing raw material/products. Refer to the Washing Hands SOP.

4. Use clean and sanitized equipment and utensils while preparing raw material/products.

5. Prepare raw materials in small batches.

MONITORING:

1. Use a clean, sanitized, and calibrated probe thermometer, preferably a thermocouple.

2. Take at least two internal temperatures from each pan of raw material/products at various stages of preparation.

3. Monitor the amount of time that raw material/products is in the temperature danger zone. It will not exceed 4 hours.

CORRECTIVE ACTIONS:

1. Retrain any raw material/products service employee found not following the procedures in this SOP.

2. Immediately return raw materials to the refrigerator if the anticipated preparation completion time is expected to exceed 30 minutes.

VERIFICATION AND RECORD KEEPING:

Raw material/products service employees will record the date, product name, start and end times of production, the two temperature measurements taken, any corrective actions taken, and the amount of raw material/products prepared on the Production Log. The extraction officer manager will verify that extraction service employees are taking the required temperatures and following the proper preparation procedure by visually monitoring raw material/products service employees during the shift and reviewing, initialing, and dating the Production Log daily. Maintain the Production Log as directed by your State agency. The raw material/products service manager will complete the raw material/products

Safety Checklist daily. The Raw material/products Safety Checklist is to be kept on file for a minimum of 5 years.

DATE IMPLEMENTED:_____ BY: _____

DATE REVIEWED:_____ BY: _____

9.13 Summary of Corrective Actions for sanitation-Based SOPs

SOP	**Corrective Action**

Cleaning Contact Surfaces	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Wash, rinse, and sanitize dirty raw material/products contact surfaces. Sanitize raw material/products contact surfaces if it is discovered that the surfaces were not properly sanitized. Discard raw material/products that comes in contact with raw material/products contact surfaces that have not been sanitized properly. 3. In a 3-compartment sink: • Drain and refill compartments periodically and as needed to keep the water clean. • Adjust the water temperature by adding hot water until the desired temperature is reached. • Add more sanitizer or water, as appropriate, until the proper sanitizer concentration is achieved. 4. In a dish machine: • Drain and refill the machine periodically and as needed to keep the water clean. • Contact the appropriate individual(s) to have the machine repaired if the machine is not reaching the proper wash temperature indicated on the data plate. • For a hot water sanitizing dish machine, retest by running the machine again. If the appropriate surface temperature is still not achieved on the second run, contact the appropriate individual(s) to have the machine repaired. Wash, rinse, and sanitize in the 3-compartment sink until the machine is repaired or use disposable single service/single-use items if a 3-compartment sink is not available. • For a chemical sanitizing dish machine, check the level of sanitizer remaining in bulk container. Fill, if needed. "Prime" the machine according to the manufacturer's instructions to ensure that the sanitizer is being pumped through the machine. Retest. If the proper sanitizer concentration level is not achieved, stop using the machine and contact the appropriate individual(s) to have it repaired. Use a 3-compartment sink to wash, rinse, and sanitize until the machine is repaired.

SOP	**Corrective Action**

Controlling Time and Temperature During Preparation Critical Control Point (CCP)	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Immediately return ingredients to the refrigerator if the anticipated preparation completion time is expected to exceed 30 minutes. 3. Discard raw material/products held in the temperature danger zone for more than 4 hours.
Date Marking	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Raw material/products that are not date marked or that exceed the 7-day time period will be discarded.
Employee Health Policy	To be determined by school officials and State or local health department.
Handling A Raw material/products Recall	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Determine if the recalled product is to be returned and to whom, or destroyed and by whom. 3. Notify feeding site staff of procedures, dates, and other specific directions to be followed for the collection or destruction of the recalled product. 4. Consolidate the recall product as quickly as possible, as but no later than 30 days after the recall notification. 5. Notify the Department 6. Follow recall procedures.

SOP	Corrective Action
Personal Hygiene	1. Retrain any raw material/products service employee found not following this procedure. 2. Discard affected raw material/products.
Preventing Contamination at Raw material/products Bars	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Remove and discard contaminated raw material/products. 3. Demonstrate to customers how to properly use utensils. 4. Discard the raw material/products if it cannot be determined how long the raw material/products temperature was above 41
Preventing Cross-Contamination during Storage and Preparation	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Separate raw material/products found improperly stored. 3.
Receiving Deliveries	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Reject the following: • Frozen raw material/products with signs of previous thawing • Sealed containers that have signs of deterioration, such as swollen sides or ends, flawed seals or seams, dents, or rust • Punctured packages • Raw material/products with outdated expiration dates •

SOP	Corrective Action
Storing and Using Poisonous or Toxic Chemicals	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Discard any raw material/products contaminated by chemicals. 3. Label and/or properly store any unlabeled or misplaced chemicals
Using and Calibrating a Thermometer	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. For an inaccurate, bimetallic, dial-faced thermometer, adjust the temperature by turning the dial while securing the calibration nut (located just under or below the dial) with pliers or a wrench. 3. For an inaccurate, digital thermometer with a reset button, adjust the thermometer according to manufacturer's instructions. 4. If an inaccurate thermometer cannot be adjusted on-site, discontinue using it, and follow manufacturer's instructions for having the thermometer calibrated. 5. Retrain employees who are using or calibrating raw material/products thermometers improperly.

SOP	Corrective Action
Washing Hands	1. Retrain any raw material/products service employee found not following the procedures in this SOP. 2. Ask employees that are observed not washing their hands at the appropriate times or using the proper procedure to wash their hands immediately. 3. Retrain employee to ensure proper hand washing procedure.

9.14 Corrective Action Log (Deviation Log)

1. Cause of Deviation

Determine and correct the cause of non-compliance;

2. Disposition of Non-Compliant Product

Determine the disposition of non-compliant product

3. Corrective Action Taken

Record the corrective actions that have been taken.

4. Measure Taken to Prevent Re-occurrence

Signature of individual performing corrective action.

Date_____
Time_____

CORRECTIVE ACTION INSTRUCTIONS AS PER NACMCF

NACMCF

"Establish corrective actions (Principle 5)

The sanitation system for raw material/products safety management is designed to identify health hazards and to establish strategies to prevent, eliminate, or reduce their occurrence. However, ideal circumstances do not always prevail and deviations from established processes may occur. An important purpose of corrective actions is to prevent raw material/products, which may be hazardous from reaching consumers. Where there is a deviation from established critical limits, corrective actions are necessary.

Therefore, corrective actions will include the following elements:

(a) Determine and correct the cause of non-compliance;

(b) Determine the disposition of non-compliant product and

(c) Record the corrective actions that have been taken.

Specific corrective actions should be developed in advance for each CCP and included in the sanitation plan. As a minimum, the sanitation plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken. Individuals who have a thorough understanding of the process, product and sanitation plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product."

Section 10: Recordkeeping

All inventory and recordkeeping will be done utilizing the "State Selected Software" Software and accompanying equipment. Inventory reconciliation modules within "State Selected Software" system support best-practices for inventory control. "State Selected Software"'s reconciliation module tracks date of reconciliation, products reconciled, reconciled amount and identifies the user performing the reconciliation. Reconciliation records are retained and can be viewed and printed at any time in the future.

10.1 Materials inventory

(a) Manufacturing, packaging, labeling and holding operations will keep written records for each shipment of component, packaging component, marijuana-derived product received from another company or individual.

(b) Records will be kept of the following:

(1) Identity of the received item, as applicable to the item; and any component number or product number if such are in use by the supplier;

(2) Supplier or vendor from which the shipment was received;

(3) Original cultivation operation, processing operation, or manufacturing operation, if known and where applicable;

(4) The cultivation operation's, processing operation's, manufacturing operation's, or supplier's batch, lot, or control number, if known and where applicable;

(5) Date of receipt; and

(6) Shipment delivery method, including where applicable the name of the commercial or private carrier.

(c) Additionally, manufacturing, packaging, and labeling operations will keep records, or establish cross references to other records such as manufacturing batch records, of the following information:

(1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the shipment;

(2) Inspection, sampling, testing, and examinations performed on the batch or lot, and the conclusions derived therefrom, as applicable to the scope of the operation;

(3) Any treatment, reprocessing, or other deviation performed by the operation on the batch or lot prior to use;

(4) Disposition of the batch or lot by The Quality Control Officer, including the date and the signature of the person responsible for approving or rejecting the batch or lot and any treatment, reprocessing, or other deviation performed thereon;

(5) A record of each use of the batch or lot in production, including:

(i) Quantity used, including unit of measure;

(ii) Name and batch, lot, or other control number of the product batch in which the batch or lot is used; and

(iii) Initials of the person(s) responsible for removing from storage the necessary quantity for use in the designated batch.

(6) A record of any portion of the batch or lot returned from production to storage, including:

(i) Quantity returned, including unit of measure;

(ii) Name and batch, lot, or other control number of the batch or lot from which the portion is returned; and

(iii) Initials of the persons responsible for verifying the quantity returned.

(7) A record of any portion of the batch or lot disposed of from storage, including the quantity, unit of measure, reason, and persons responsible for measuring the quantity.

(8) A complete and accurate record of all plant stock or products of marijuana on hand will be prepared weekly as well a comprehensive inventory performed annually on the anniversary of the initial inventory. “State Selected Software”’s custom reporting engine allows for custom, filterable, reports to be built and exported from the system. This includes reports showing the amount of medical marijuana and the number of plants at the cultivation center at any given point in time. Comprehensive plant records and cultivation reporting tools enable the Cultivation Agent in Charge and Quality Control Officer to review plant reports and reconcile against

physical plant inventory on a regular basis. “State Selected Software”’s reporting and reconciliation reports support best practices of weekly and annual physical plant inventories.

10.2 Logistics

(a) Manufacturing, packaging, labeling and holding operations will keep written records for each batch or lot of marijuana-derived product distributed by the operation.

(b) Records will be kept of the following:

(1) Identity of the marijuana-derived product, and any item code or product number if such are in use by the manufacturing, packaging, labeling, or holding operation;

(2) A record of each distribution of the batch or lot, including:

(i) Quantity distributed, including unit of measure;

(ii) Name and address of each company or non-profit entity to which, or individual to whom, the batch is distributed, unless a system exists to unambiguously cross-reference the name to the corresponding address maintained on file separately;

(iii) Shipping method by which each shipment is distributed, including where applicable the name of the commercial or private carrier;

(iv) Initials of the persons responsible for removing from storage the necessary quantity for each shipment. Each distribution will be verified by a second person.

(3) A record of any portion of the batch or lot returned to storage, including:

(i) Quantity returned, including the unit of measure;

(ii) Company, non-profit entity, individual, or location from which the portion is returned;

(iii) Shipment return method, including where applicable the name of the commercial or private carrier;

(iv) Initials of the person(s) responsible for verifying the quantity returned;

(4) A record of any portion of the batch or lot disposed of from storage, including the quantity, unit of measure, reason, and persons responsible for

measuring the quantity.

(c) Additionally, manufacturing, packaging, and labeling operations will keep records or establish cross references to other records such as manufacturing batch records, for the following:

(1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the batch or lot;

(2) Inspection, sampling, testing, and examinations performed on the batch or lot by the operation, and the conclusions derived therefrom;

(3) Any treatment, reprocessing, or other deviation performed on the batch or lot by the operation prior to distribution; and

(4) Disposition of the batch or lot by the Quality Control Officer, including the date and the signature of the person responsible for approving the batch or lot for distribution; and the date and the signature of the person responsible for approving or rejecting any treatment, reprocessing, or other deviation performed thereon.

10.3 Reconciliation

(a) Records of receipt, use or distribution, return, and disposal of each batch or lot of components, packaging components, marijuana-derived products will be kept chronologically, and the quantities will be recorded with an appropriate level of precision.

(b) After each batch or lot is used or distributed, manufacturing, packaging, labeling, and holding operations will perform a reconciliation of the quantity received into storage against the quantity used, distributed, returned, and/or disposed. Such calculations will be performed by one person and independently verified by a second person.

(c) Narrow limits will be established, based where possible on historical operating data, for the amount of allowed variation in the reconciliation.

(d) When a reconciliation falls outside the allowed limits, the Quality Control Officer will conduct an investigation to determine, to the extent possible, the source of the discrepancy. The deviation will be documented, explained, and approved by the Quality Control Officer.

(e) “State Selected Software”’s reconciliation module tracks date of reconciliation, products reconciled, reconciled amount and identifies the user performing the

reconciliation. Reconciliation records are retained and can be viewed and printed at any time in the future.

10.4 Record retention

The following records will be kept and maintained on the permitted premises for a five-year period and will be made available for inspection if requested utilizing the "State Selected Software" wholesale sales and distribution functionalities tracking system.

1. The date of each sale or distribution to a dispensary;

2. The name, address and registration number of the dispensary;

3. The item number, product name (description), and quantity of marijuana infused products registered by the regulatory body and sold or otherwise distributed to the dispensary.

4. The price charged and the amount received for the marijuana-infused products.

5. Purchase invoices, bills of lading, manifests, sales records, copies of sale and supporting documents, including the items and/or services purchased from whom the items were purchased and the date of the purchase;

6. If applicable, bank statements and canceled checks for all accounts relating to the cultivation center

7. Accounting and tax records relating to the cultivation center and each producer backer;

8. Records of all financial transactions related to the cultivation center, including contracts and/or agreements for services performed or that relate to the cultivation center.

9. All employee records, including training, education, discipline, etc.;

10. Soil amendment, fertilizers, pesticides, and other crop production aids applied to the growing medium or plants or used in the growing process of growing marijuana;

11. Production records, including:
    A. All plants being cultivated on a daily basis
    B. Planting, harvest and curing, weighing, destruction of marijuana, creating batches of marijuana-infused products and labeling; and
    C. Disposal of marijuana infused products and waste material associated with production.

12. Records of each batch of extracts made, including, at a minimum the usable marijuana or trim leaves, and other plant material, used (including the total weight of the base product

used), any solvents or other compounds utilized, and the product weight of the end product produced.

13. Transportation and shipping manifest records.

14. Inventory records.

15. Records of all samples sent to an independent testing lab and the quality assurance test results;

16. Records of all samples sent to an independent testing lab and the quality assurance test results

17. All samples provided to anyone or any entity for any purpose; and

18. Records of any theft, loss or other unaccountability of any marijuana seedlings, clones, plants, trim or other plant material, or extracts.

19. All returned product complaints and recall events.

Gerald Joseph Fetterly Jr. – 2015

PERMANENT MAILING ADDRESS

[redacted]

Home: [redacted]

Cell: [redacted]

WORK ADDRESS

[redacted]

EDUCATION

Doctor of Philosophy, Pharmaceutics, *June 2000*

University at Buffalo, School of Pharmacy, State University of New York

Graduate Advisor: Dr. Robert M. Straubinger

Master's of Science, Pharmaceutics, *February 1997*

University at Buffalo, School of Pharmacy, State University of New York

Bristol-Myers Squibb Pharmaceutical Research Institute, Buffalo, NY

Graduate Advisor: Dr. Kenneth M. Tramposch

Bachelor of Arts, Chemistry, *1994*

University at Buffalo, State University of New York

Graduate Advisor: Dr. Kenneth Takeuchi

PROFESSIONAL EMPLOYMENT AND RESEARCH EXPERIENCE:

[redacted]

University at Buffalo, SUNY

- Assistant Professor, Department of Pharmaceutical Sciences, *August 2012 - Present*

[redacted]

[redacted]

Food and Drug Administration, Office of Clinical Pharmacology and Biopharmaceutics

- Clinical Pharmacologist, *May 2000 – May 2002*

University at Buffalo, State University of New York, School of Pharmacy, Department of Pharmaceutics, *August 1994 – May 2000*

- Didactic course work and seminars in the areas of pharmaceutics, pharmacokinetics, pharmacodynamics, PK/PD modeling, metabolism, drug delivery, membrane transport and diffusion, pharmaceutical biotechnology, pharmaceutical and biophysical analysis, pharmacology, small animal surgery, and statistics.

[redacted]

MENTORING

Post-Doctoral Associates

- Urvi Aras, PhD, 2009-2011; was trained and mentored in the fields of translational and clinical pharmacology, drug development, PK/PD modeling, and pharmacometrics
- Nan Zheng, PhD, 2011-2012; was trained and mentored in the fields of translational and clinical pharmacology, drug development, PK/PD modeling, and pharmacometrics
- Biao Liu, PhD, 2011-2012; was trained and mentored in the fields of translational and clinical pharmacology, drug development, PK/PD modeling, and pharmacometrics
- Allison Gaudy, PhD, 2012-2013; was trained and mentored in the fields of translational and clinical pharmacology, drug development, PK/PD modeling, and pharmacometrics
- Laura Pitzonka, PhD, 2013-2014; was trained and mentored in the fields of translational and clinical pharmacology, drug development, PK/PD modeling, and pharmacometrics

Graduate Students

- Dipti Pawaskar, PhD, 2010 – 2012; assisted in co-mentoring during her thesis work in

collaboration with the Department of Pharmaceutical Sciences, University at Buffalo.

- Ashley Ditmar, 2011-2014; currently serve on thesis committee for investigation of genetic correlations with irinotecan-related toxicities, Department of Cancer Genetics, Roswell Park Cancer Institute Graduate Division of University at Buffalo.
- Krista Pundt, 2013-present; serve as her primary advisor and mentor for doctoral thesis on investigation of novel pharmacological agents for the treatment of leukemia, Department of Molecular Pharmacology and Therapeutics, Roswell Park Cancer Institute Graduate Division of University at Buffalo.

TRAINING

- Certificate of Leadership Training, Canisius College School of Management, *June 2007*
- PK/PD Modeling
  - ADAPT 5, Phoenix WinNonlin, and NONMEM
  - NONMEM internal training course at Cognigen Corporation
  - WinPOPT
  - NONMEM training course on categorical and binary variables
  - Splus GUI and SAS training
- Training in GLP and GMP guidelines.
- Preparation of formulations such as liposomes using lyophilization or thin film method.
- Pharmaceutical analysis experience includes: particle size analysis using laser light scattering, UV-Vis spectroscopy, colorimetric assays, HPLC with UV and □-flow detection, size-exclusion chromatography, thin layer chromatography, Circular Dichroism, fluorescence, pH, osmolarity, light microscopy, XRF (X-ray fluorescence), solubility testing, stability testing, centrifugation procedures, and radiolabeled receptor assays using 3H or 125I.
- Pharmaceutical processing experience includes: liquid-liquid extraction, solid phase extraction, and tissue homogenization.
- Cell culture: growth inhibition studies of cancer cell lines.
- Animal dosing: topical and intravenously.

PROFESSIONAL AND SCIENTIFIC ORGANIZATIONS

- American Society of Clinical Oncology (ASCO) member, *2004-present*
- American Association for Cancer Research (AACR) member, *2004-present*
- American Association of Pharmaceutical Scientists (AAPS) member, *1997-present*
- American Society of Clinical Pharmacology and Therapeutics (ASCPT) member, *2013-present*

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AWARDS

- FDA Science Day, 2nd place for presentation, *2001*
- Pharmaceutical Research and Manufacturers of America (PhRMA) Fellowship, *1999-2000*
- Bristol-Myers Squibb Pharmaceutical Research Institute Fellowship, *1994-1996*

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Manuscripts:

1. Infante, J.R., *et al.* Phase 1b study of the oral gemcitabine 'Pro-drug' LY2334737 in combination with capecitabine in patients with advanced solid tumors. *Invest New Drugs* **33**, 432-439 (2015).
2. Adelaiye, R., *et al.* Sunitinib dose escalation overcomes transient resistance in clear cell renal cell carcinoma and is associated with epigenetic modifications. *Mol Cancer Ther* **14**, 513-522 (2015).
3. Tornatore, K.M., *et al.* Influence of sex and race on mycophenolic acid pharmacokinetics in stable African American and Caucasian renal transplant recipients. *Clin Pharmacokinet* **54**, 423-434 (2015).
4. Wilton, J., *et al.* Pharmacokinetic analysis of the FAK scaffold inhibitor C4 in dogs. *Eur J Drug Metab Pharmacokinet* (2014).
5. Ngamphaiboon, N., *et al.* A phase I study of the histone deacetylase (HDAC) inhibitor entinostat, in combination with sorafenib in patients with advanced solid tumors. *Invest New Drugs* **33**, 225-232 (2015).
6. Kim, W., *et al.* Sequential use of the androgen synthesis inhibitors ketoconazole and abiraterone acetate in castration-resistant prostate cancer and the predictive value of circulating androgens. *Clin Cancer Res* **20**, 6269-6276 (2014).
7. Wilton, J.H., Titus, M.A., Efstathiou, E., Fetterly, G.J. & Mohler, J.L. Androgenic biomarker prof|ling in human matrices and cell culture samples using high throughput, electrospray tandem mass spectrometry. *Prostate* **74**, 722-731 (2014).
8. McCann, S.E., *et al.* A pilot study comparing the effect of flaxseed, aromatase inhibitor, and the combination on breast tumor biomarkers. *Nutr Cancer* **66**, 566-575 (2014).
9. Fong, M.K., Fetterly, G.J., Jr., McDougald, L.J. & Iyer, R.V. Carboplatin pharmacokinetics in a patient receiving hemodialysis. *Pharmacotherapy* **34**, e9-13 (2014).
10. Fetterly, G.J., *et al.* Utilizing pharmacokinetics/pharmacodynamics modeling to simultaneously examine free CCL2, total CCL2 and carlumab (CNTO 888) concentration time data. *J Clin Pharmacol* **53**, 1020-1027 (2013).
11. Fetterly, G.J., *et al.* Development of a preclinical PK/PD model to assess antitumor response of a sequential aflibercept and doxorubicin-dosing strategy in acute myeloid leukemia. *AAPS J* **15**, 662-673 (2013).
12. Pawaskar, D.K., *et al.* Synergistic interactions between sorafenib and everolimus in pancreatic cancer xenografts in mice. *Cancer Chemother Pharmacol* **71**, 1231-1240 (2013).
13. Pawaskar, D.K., *et al.* Physiologically based pharmacokinetic models for everolimus and sorafenib in mice. *Cancer Chemother Pharmacol* **71**, 1219-1229 (2013).
14. Naing, A., *et al.* A phase I trial of KX2-391, a novel non-ATP competitive substrate-pocket- directed SRC inhibitor, in patients with advanced malignancies. *Invest New Drugs* **31**, 967-973 (2013).
15. Antonarakis, E.S., *et al.* A phase 2 study of KX2-391, an oral inhibitor of Src kinase and tubulin polymerization, in men with bone-metastatic castration-resistant prostate cancer. *Cancer Chemother Pharmacol* **71**, 883-892 (2013).
16. Pawaskar, D.K., Straubinger, R.M., Fetterly, G.J., Ma, W.W. & Jusko, W.J. Interactions of everolimus and sorafenib in whole blood lymphocyte proliferation. *Pharm Res* **30**, 707-713 (2013).
17. Pawaskar, D.K., Straubinger, R.M., Fetterly, G.J., Ma, W.W. & Jusko, W.J. Interactions of everolimus and sorafenib in pancreatic cancer cells. *AAPS J* **15**, 78-84 (2013).
18. Thudium, K.E., *et al.* Synergism between clofarabine and decitabine through p53R2: a pharmacodynamic drug-drug interaction modeling. *Leuk Res* **36**, 1410-1416 (2012).
19. Weickhardt, A., *et al.* A phase I/II study of erlotinib in combination with the anti-insulin-like growth factor-1 receptor monoclonal antibody IMC-A12 (cixutumumab) in patients with advanced non-small cell lung

cancer. *J Thorac Oncol* **7**, 419-426 (2012).
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23. Iyer, R., Fetterly, G., Lugade, A. & Thanavala, Y. Sorafenib: a clinical and pharmacologic review. *Expert Opin Pharmacother* **11**, 1943-1955 (2010).
24. Fakih, M.G., *et al.* A phase I, pharmacokinetic, and pharmacodynamic study of two schedules of vorinostat in combination with 5-fluorouracil and leucovorin in patients with refractory solid tumors. *Clin Cancer Res* **16**, 3786-3794 (2010).
25. Tummala, R., *et al.* Combination effects of platinum drugs and N1, N11 diethylnorspermine on spermidine/spermine N1-acetyltransferase, polyamines and growth inhibition in A2780 human ovarian carcinoma cells and their oxaliplatin and cisplatin-resistant variants. *Cancer Chemother Pharmacol* **67**, 401-414 (2011).
26. Fakih, M.G., *et al.* A phase I, pharmacokinetic and pharmacodynamic study on vorinostat in combination with 5-fluorouracil, leucovorin, and oxaliplatin in patients with refractory colorectal cancer. *Clin Cancer Res* **15**, 3189-3195 (2009).
27. Ailawadhi, S., *et al.* Erlotinib for metastatic non-small-cell lung cancer: first-, second- or third-line setting - does it matter ? A single-institution experience. *Oncology* **76**, 85-90 (2009).
28. Fetterly, G.J., *et al.* Pharmacokinetic/pharmacodynamic modeling and simulation of neutropenia during phase I development of liposome-entrapped paclitaxel. *Clin Cancer Res* **14**, 5856-5863 (2008).
29. Mita, M.M., *et al.* Phase I trial of the novel mammalian target of rapamycin inhibitor deforolimus (AP23573; MK-8669) administered intravenously daily for 5 days every 2 weeks to patients with advanced malignancies. *J Clin Oncol* **26**, 361-367 (2008).
30. Fetterly, G.J., *et al.* Semimechanistic pharmacokinetic/pharmacodynamic model for hepatoprotective effect of dexamethasone on transient transaminitis after trabectedin (ET-743) treatment. *Cancer Chemother Pharmacol* **62**, 135-147 (2008).
31. Fetterly, G.J., *et al.* Pharmacokinetics of oritavancin in plasma and skin blister fluid following administration of a 200-milligram dose for 3 days or a single 800-milligram dose. *Antimicrob Agents Chemother* **49**, 148-152 (2005).
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33. Lorenz, S.A., *et al.* Noncovalent dimerization of paclitaxel in solution: evidence from electrospray ionization mass spectrometry. *J Pharm Sci* **91**, 2057-2066 (2002).
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Abstracts and Presentations:

1. "Comparison of the Skin Pharmacokinetics of Three Calcipotriene Formulations." GJ Fetterly and KM Tramposch. An abstract and poster presented at the 1997 Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS) in Boston, MA, November 1997 and at the 1997 Sigma Xi Student Research Competition, University at Buffalo, Buffalo, NY, April 1997.

2. "Pharmacodynamics of Paclitaxel: Relationship of Antitumor Efficacy to the Duration of Drug Exposure." GJ Fetterly and RM Straubinger. An abstract and poster presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS) in San Francisco, CA, November 1998 and at the 1998 Sigma Xi Student Research Competition, University at Buffalo, Buffalo, NY, April 1998.

3. "Pharmaceutical Evaluation of Paclitaxel in Liposomes." GJ Fetterly and RM Straubinger. An abstract and poster presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS) in New Orleans, LA, November 1999.
4. "Comparative Pharmacokinetics and Pharmacodynamics of Paclitaxel Formulations." GJ Fetterly and RM Straubinger. Presented at the 2001 FDA Science Day in Rockville, MD, November 2001.
5. "Characterization of Oritavancin (ORI) Pharmacokinetics (PK) in Plasma and Blister Fluid in Normal Healthy Volunteers." GJ Fetterly, C Ong, SM Bhavnani, JS Loutit, SB Porter, PG Ambrose, and DP Nicolau. Presented at the 2003 Interscience Conference for Antiinfective Agents and Chemotherapy (ICAAC) in Chicago, IL, September 2003.
6. "Pharmacogenomic and Pharmacokinetic Assessment of Liposome Encapsulated SN-38 (LE-SN38) in Advanced Cancer Patients." EH Kraut, MN Fishman, PM LoRusso, JL Steinberg, JA Nieves, GJ Fetterly, IM Darling, SP Wanaski, JL Dul, JW Sherman. Presented at the 2004 American Society of Clinical Oncology (ASCO) in New Orleans, LA, June 2004: 2501.
7. "Exposure-Response in Oncology Drug Development." GJ Fetterly. Presented at the SMi Global Cancer Event, London, England, June 2004.
8. "Effect of Hepatic Impairment on the Pharmacokinetics of the Novel Glycopeptide Oritavancin." GJ Fetterly, JS Owen, SM Bhavnani, PG Ambrose, L Morello, JS Loutit, and SB Porter. Presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS) in Baltimore, MD, November 2004.
9. "Final Results of a Phase I Study of Liposome Entrapped Paclitaxel (LEP-ETU) in Patients with Advanced Cancer" N Damjanov, MN Fishman, JL Steinberg, GJ Fetterly, A Haas, A Grahn, C Lauay, JL Dul, JW Shewman, EH Rubin. Presented at the 41st Annual ASCO Meeting in Orlando, FL, May 2005: 2048.
10. "Final Results of a Phase I Study of Liposome Encapsulated SN-38 (LE-SN38): Safety, Pharmacogenomics. Pharmacokinetics, and Tumor Response" EH Kraut, MN Fishman, PM LoRusso, MS Gordon, EH Rubin, A Haas, GJ Fetterly, P Cullinan, JL Dul, JL Steinberg. Presented at the 41st Annual ASCO Meeting in Orlando, FL, May 2005: 2017.
11. "Development of a Pharmacokinetic (PK) Model and Assessment of Patient (Pt) Covariate Effects on Dose-Dependent PK Following Different Dosing Schedules in Two Phase I Trials of AP23573 (AP), An mTOR Inhibitor" AA Desai, M Mita, GJ Fetterly, C Chang, M Netsch, HL Knowles, CL Bedrosian, E Rowinsky, A Tolcher, MJ Ratain. Presented at the 41st Annual ASCO Meeting in Orlando, FL, May 2005: 3043.
12. Model Based Drug Development in Oncology. GJ Fetterly, TH Grasela. Presented at Changing the Paradigm in Oncology Drug Development Course, Pharmaceutical Education and Research Institute, Arlington, VA, January 30, 2006.
13. "Results of a clinical pharmacokinetic (PK) bioequivalence (BE) study of liposomal paclitaxel (LEP-ETU) versus paclitaxel (T) in patients with advanced cancer" AR Tan, AR Hanauske, H Gelderblom, ME Scheulen, LJ Van Warmerdam, H Rosing, GJ Fetterly, VS Shu, JW Sherman, EH Rubin, LEP-ETU PK BE study team. Presented at the 42nd Annual ASCO Meeting in Atlanta, GA, June 2006: 2017.
14. "Modeling and simulation of neutropenia to support dosing regimens for liposome-encapsulated paclitaxel easy-to-use (LEP- ETU)**"** TH Grasela, GJ Fetterly, JL Dul, D LeComte, AY Grahn, JB Fiedler-Kelly, JW Sherman, N Damjanov, MN Fishman and AR Tan. Presented at the 43rd Annual ASCO Meeting in Chicago, Ill, June 2007: 13011.
15. "Mechanism-based PKPD model for hepatoprotective effect of dexamethasone on transient transaminitis after trabectedin (ET- 743) treatment" GJ Fetterly, JS Owen, K Stuyckens, JA Passarell, P Zannikos, AS Matos, MA Izquierdo and JJ Perez-Ruixo. Presented at the 43rd Annual ASCO Meeting in Chicago, Ill, June 2007: 2545.
16. "Woodchuck hepatocellular cancer (HCC): a translational model for developing anti-angiogenic therapies for human hepatocellular cancer" R Iyer, B Tennant, R Brekken, L Rivera, L Pendyala, Z Wu, GJ Fetterly, C Johnson, and D Trump. Presented at the 99th AACR Meeting in San Diego, CA, Apr 2008: 2916.

17. "Pharmacokinetics of oral deforolimus" G. J. Fetterly, M. M. Mita, C. D. Britten, E. Poplin, W. D. Tap, A. Carmona, L. Yonemoto, C. L. Bedrosian, E. H. Rubin, A. W. Tolcher. Presented at the 44th Annual ASCO Meeting in Chicago, Ill, June 2008: 14555.
18. "VEGF-Trap (aflibercept) improves systemic delivery of doxorubicin to marrow and extramedullary leukemia disease sites in a preclinical model" D Lal, A Sen, M Murphy, J Prey, GJ Fetterly, ES Wang. Presented at the 100th Annual AACR Meeting in Denver, CO, April 2009.
19. Adjei AA, Cohen RB, Kurzrock R, et al: Results of a phase I trial of KX2-391, a novel non-ATP competitive substrate-pocket directed SRC inhibitor, in patients with advanced malignancies. ASCO Meeting Abstracts 27:3511, 2009
20. Fakih MG, Pendyala L, Egorin MJ, et al: A phase I clinical trial of vorinostat in combination with sFULV2 in patients with refractory solid tumors. ASCO Meeting Abstracts 27:4083, 2009
21. Fetterly GJ, Brady WE, LeVea CM, et al: A phase I pharmacokinetic (PK) study of vorinostat (V) in combination with irinotecan (I), 5-fluorouracil (5FU), and leucovorin (FOLFIRI) in advanced upper gastrointestinal cancers (AGC). ASCO Meeting Abstracts 27:e15540, 2009
22. Fetterly GJ, Puchalski TA, Takimoto CH, et al: Utilizing mechanistic PK/PD modeling to simultaneously examine free CCL2, total CCL2, and CNTO 888 serum concentration time data. ASCO Meeting Abstracts 28:3029, 2010
23. Iyer RV, Fetterly GJ, Javle MM, et al: Enhanced gemcitabine (G) exposure in combination with escalating doses of paricalcitol [19-nor-1 alpha, 25-(OH)2 D2] (P) in patients with advanced malignancies. ASCO Meeting Abstracts 28:e13031, 2010
24. Khushalani NI, Fetterly GJ, Iyer RV, et al: Phase I study of sunitinib with irinotecan/5-fluorouracil/ leucovorin (FOLFIRI) for advanced gastroesophageal cancers. ASCO Meeting Abstracts 28:TPS201, 2010
25. Adjei AA, Sosman JA, Dy GK, et al: A phase I dose-escalation trial evaluating ARQ 197 administered in combination with sorafenib in adult patients (pts) with advanced solid tumors. ASCO Meeting Abstracts 28:3024, 2010
26. "Ultrasensitive Quantitation of the EGFR Inhibitor, Erlotinib and its Active Metabolite OSI-420 Using LC/MS/MS. Kimberly Clark MS; Joshua Prey MS; Ping Wang PhD; Alex Adjei MD PhD; Gerald Fetterly PhD. Presented at the 24th Annual AAPS Conference, New Orleans, November 2010.
27. Adjei AA, Sosman JA, Martell RE, et al: Efficacy in selected tumor types in a phase I study of the c-MET inhibitor ARQ 197 in combination with sorafenib. ASCO Meeting Abstracts 29:3034, 2011
28. Fetterly GJ, Thudium KE, Kalabus J, et al: Understanding the role of carbonyl reductase polymorphisms on doxorubicin-induced cardiotoxicity with population pharmacokinetics (PK). ASCO Meeting Abstracts 29:2606, 2011
29. Ait-Oudhia S, Mager DE, Tomaszewski G, et al: Bridging sunitinib exposure to time-to-tumor progression in hepatocellular carcinoma patients with mathematical modeling of an angiogenic biomarker. ASCO Meeting Abstracts 30:e14690, 2012
30. Antonarakis ES, Heath EI, Posadas EM, et al: A phase II study of KX2-391, an oral inhibitor of Src kinase and tubulin polymerization, in men with bone-metastatic castration-resistant prostate cancer (CRPC): A PCCTC trial. ASCO Meeting Abstracts 30:4654, 2012
31. Fetterly GJ, Liu B, Senzer NN, et al: Clinical pharmacokinetics of the Smac-mimetic birinapant (TL32711) as a single agent and in combination with multiple chemotherapy regimens. ASCO Meeting Abstracts 30:3029, 2012
32. Iyer RV, Tomaszewski G, Wu YV, et al: Advanced hepatocellular carcinoma (HCC) treated with sunitinib (Su) and transarterial chemoembolization (TACE): Phase II trial final report. ASCO Meeting Abstracts 30:275, 2012

33. Martell RE, Puzanov I, Ma WW, et al: Safety and efficacy of MET inhibitor tivantinib (ARQ 197) combined with sorafenib in patients (pts) with hepatocellular carcinoma (HCC) from a phase I study. ASCO Meeting Abstracts 30:4117, 2012

34. Means-Powell JA, Adjei AA, Puzanov I, et al: Safety and efficacy of MET inhibitor tivantinib (ARQ 197) combined with sorafenib in patients (pts) with NRAS wild-type or mutant melanoma from a phase I study. ASCO Meeting Abstracts 30:8519, 2012

Tab 4

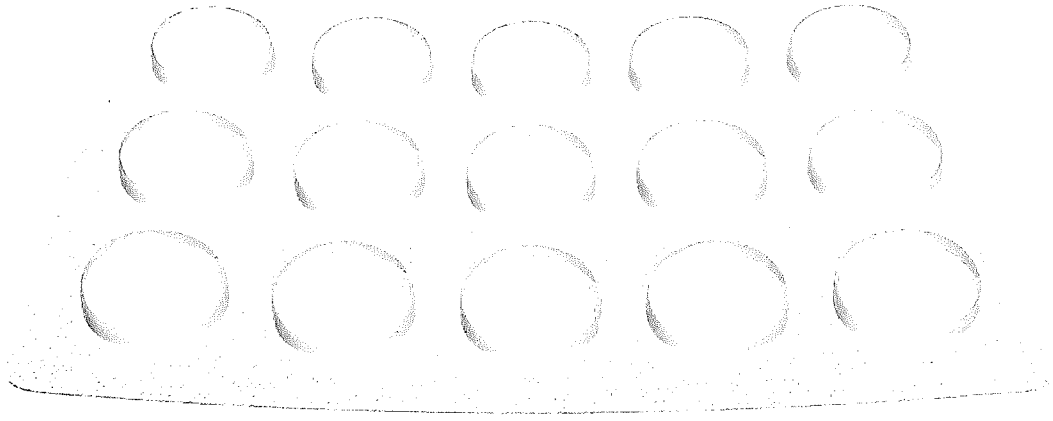
Location of Non Refundable and Conditionally Refundable Registration Fees

In the original application, the checks for the required fees appear in Tab 1 immediately behind the application's letter of introduction. In all copies of the application, copies of the checks for the application fees have been inserted in Tab 1.

Section 4: Devices

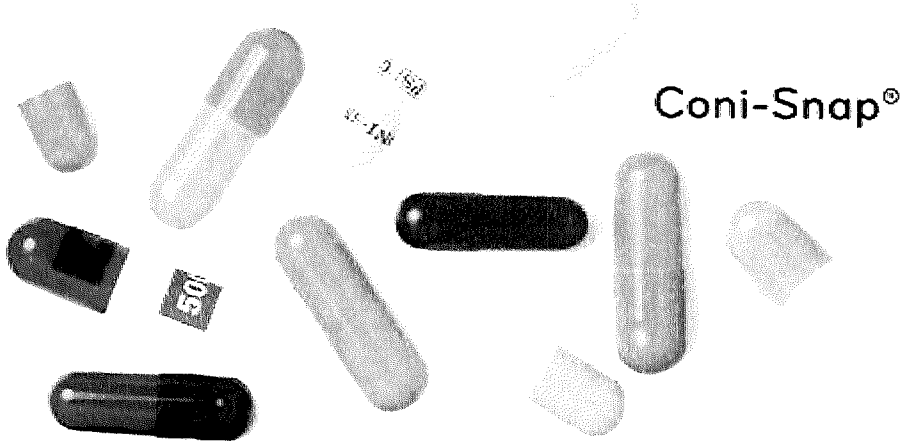
Redacted pursuant to N.Y. Public Officers Law, Art.6

Ford Transit Hardened/Armored Vehicle	



Coni-Snap Hard Gelatin Capsules

Coni-Snap® capsules, the world's most popular two-piece hard gelatin capsules.

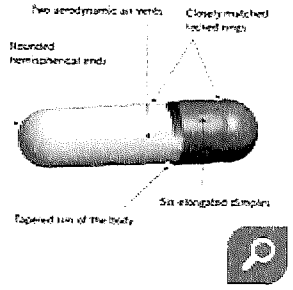


Renowned Performance

For several decades, Coni-Snap hard gelatin capsules (HGCs) have been a product of choice for pharmaceuticals and health care companies due to their reliable, outstanding performance worldwide.

Product Features & Options

Coni-Snap capsules are the most widely used capsule in the world for many reasons. Key capsule features and benefits include:

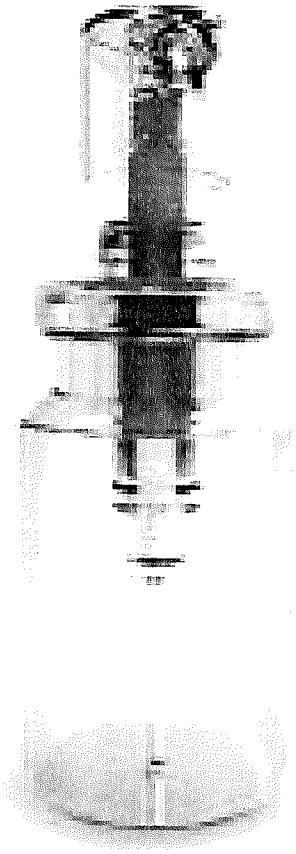


Coni-Snap® capsules
Designed to Perform

- Tapered rim of the body engages easily with the cap allowing for problem-free closure
- A dual snap-ring locking system provides full circumference leak-free containment
- Air vents allow air to escape during filling on high-speed capsule filling machines
- Rounded hemispherical ends are stronger and more resistant to deformation

- Available in a wide array of sizes
- Customizable with color and printing
- Suitable for a wide range of formulations for both pharmaceuticals and health and nutrition products
- Outstanding quality – manufactured in accordance with cGMP guidelines
- Certified quality assurance system for traceability of raw materials

Aptar VP7 Oral Mucosal Spray



- Delivers an exact 100 microliter spray each time for accurate dosing.
- Oral Mucosal deliverance allows for quicker deliverance into blood stream for faster relief.

- Unique delivery mechanism allows for a range of precise cannabinoid mixtures (THC, CBD, CND, etc.) unobtainable from single plant strain.

Vaporizer Pens

Special Note:

We do not show a vaporizer pen in this document because we do not believe there is a device that meets the strict interpretation of "measured dose" on a consistent basis. We do not believe using even a liberal definition of the FDA requirement any of the available devices would meet the standards.

Therefore Kinex Supportive Pharmaceuticals has developed (using our proprietary knowledge) developed a Marijuana extraction "Pellet" This pellet will contain precisely the amount of dose that is called for in the certification as labeled. This pellet can be used in any number of commercially available vaporizing devices.

This pellet would be fully consumed at a single time representing the correct and accurate dose uptake.

The pellet will be packaged in the blister pack representing a month supply. These blister packs are child proof and meet all standards.

LETTER OF INTENT TO LEASE OR SELL/PURCHASE

May 28, 2015

Location:	2303 Hamburg Turnpike Lackawanna, NY 14218
Seller/ Lessor:	1951 Hamburg Turnpike, LLC 2558 Hamburg Turnpike Suite 300 Lackawanna, NY 14218
Buyer/Lessee:	Kinex Supportive Pharmaceuticals, LLC c/o Kinex Pharmaceuticals, Inc. 701 Ellicott Street Buffalo, NY 14203
Premises:	Approximately 4.57 acre portion of Sub-Parcel III-4 including steel clad, steel frame, single story, high-bay, clear span 32,500 sq.ft. structure commonly referred to as the South Electric Stores Building
Commencement Date:	To be determined but not later than August 15, 2015.
Use:	Manufacturing Space for production of medical marijuana.
Internet Accessibility	Yes _X_ No ____ Service Provider: _Verizon_____

SELLER/LESSOR
1951 Hamburg Turnpike, LLC

By: _____

Date:

PURCHASER/LESSEE:
Kinex Supportive
Pharmaceuticals, LLC

By: _____

Date: 6/1/2015

LETTER OF INTENT TO LEASE

May 22, 2015

Location: Name BENBRO PARK
Address 81 BENBRO DR. CHEEK. N.Y. 14225

Landlord: Name BENDERSON DEV. Co., LLC
Address 570 DELAWARE AVE BFLO. N.Y. 14202

Tenant: Kinex Supportive Pharmaceuticals, LLC
c/o Kinex Pharmaceuticals, Inc.
701 Ellicott Street
Buffalo, NY 14203

Premises: Location, consisting of 1581 sq. ft.

Commencement Date: To be determined ~~but not later than August 1, 2015~~

Term ~~and Gross~~ & Rental Rate: Five (5) year term - $13.00 psf plus electric/Heat / WATER PAID BY TENANT TO SUPPLIER
~~Ten (10) year term - $.50 psf plus~~
BASE

Rental Rate Annual Increase: Three percent (3%) per year of base rental rate

Security Deposit: $5,000.—

Use of Premises: ~~Retail Space for~~ dispensing of medical marijuana, BASED UPON TOWN APPROVAL

Landlord Work: N/A

Tenant Work: Tenant improvements to be done in accordance with the plans provided by Architect, to be mutually agreed upon by Landlord and Tenant. Tenant to be responsible for cost of all build outs and improvements. ~~Landlord and Tenant to agree upon a commercially reasonable bailout plan prior to execution of lease.~~

Internet Accessibility Yes ✓ No ___ Service Provider VERIZON

Additional Matters: Landlord acknowledges the following is legally required of Tenant by New York State. The definitive lease will provide (a) that Landlord's rights of reentry into the Premises will prohibit Landlord from manufacturing and/or dispensing medical marihuana on the Premises in accordance with Article 33 of the Public Health Law and (b) ~~Landlord~~ will provide the New York State Department of Health, Mayor Erastus Corning 2nd Tower, The Governor Nelson A. Rockefeller 29 Empire State Plaza, Albany, N.Y. 12237, ~~with~~

TENANT

~~notification by certified mail of its intent to reenter the Premises or to initiate dispossess proceeding or~~ that the lease is due to expire, at least 30 days prior to the date on which the Landlord intends to exercise a right of reentry or to initiate such proceedings ~~or at least 60 days before expiration of the lease.~~ .

WITH 3% INC. EA YR.

* Annual Operating Expenses — [CAM Charges? Snow removal, etc?] CAM: $1.00/S.F. FOR EXTERIOR REPAIRS AND REPLACEMENT. TENANT RESP. FOR DAY TO DAY WITH SNOW AND ICE REMOVAL.

Broker — Landlord and Tenant each warrant that in connection with this lease of the Premises, they have not employed or dealt with any broker, agent or finder.

Legal Fees — Lessee shall be solely responsible for all legal fees associated with the preparation of this Letter of Intent and all additional lease documents prepared for the Premises.

~~Lessor's counsel shall prepare a draft of the Lease and deliver it to Lessee's attorney promptly after execution hereof.~~ The foregoing provisions of this Letter of Intent shall be non-binding upon the parties; however, the parties shall negotiate diligently and in good faith in an effort to agree on the Lease based upon the terms of this letter of intent. ~~Upon execution of the Lease, this letter of intent shall be merged therein.~~ AND FINAL APPROVAL BY LANDLORD.

LANDLORD:

By: EXEC DIR. LEMING

Date: 5/28/15

TENANT: Kinex Supportive Pharmaceuticals, LLC

By:

Date: 6/1/2015

* PROPERTY TAXES: TENANT TO PAY PRO-RATA SHARE ESTIMATED @ $1.03/S.F.

* FIRE/LIABILITY INS.: TENANT TO PAY $.75/S.F. FOR FIRST YR. WITH 3% INCREASES EA. YR.

LETTER OF INTENT TO LEASE

May 22, 2015

Location:	Corporate Woods Retail Center 26 Corporate Woods, Rochester New York 14623
Landlord:	~~Spall Management Corporation~~ Corporate Woods Associates, LLC. 175 Corporate Woods, Suite 160 Rochester, New York 14623
Tenant:	Kinex Supportive Pharmaceuticals, LLC c/o Kinex Pharmaceuticals, Inc. 701 Ellicott Street Buffalo, NY 14203
Premises:	Location, consisting of approximately, 1,200sq. ft., Store 18
Commencement Date:	To be determined but not later than August1, 2015.
Term and Gross Rental Rate:	Five (5) year term - $18.75 psf plus cleaning and all utilities Ten (10) year term - $18.50 psf plus cleaning and all utilities
Rental Rate Annual Increase:	Three percent (3%) per year of base rental rate
Security Deposit:	Equal to 2 months Base Rent
Use of Premises:	Retail Space for dispensing of medical marijuana.
Landlord Work:	N/A
Tenant Work:	Tenant improvements to be done in accordance with the plans provided by Architect, to be mutually agreed upon by Landlord and Tenant. Tenant to be responsible for cost of all build outs and improvements, Landlord and Tenant to agree upon a commercially reasonable bailout plan prior to execution of lease. to be completed by Landlord Contractors
Internet Accessibility	Yes X Service Provider: Time Warner & Frontier
Additional Matters:	Landlord acknowledges the following is legally required of Tenant by New York State. The definitive lease will provide (a) that Landlord's rights of reentry into the Premises will prohibit Landlord from manufacturing and/or dispensing medical marihuana on the Premises in accordance with Article 33 of the Public Health Law and (b) Landlord will provide the New York State Department of Health, Mayor Erastus Corning 2nd Tower, The Governor Nelson A. Rockefeller 29 Empire State Plaza, Albany, N.Y. 12237, with notification by certified mail of its intent to reenter the Premises or to initiate dispossess proceeding or that the lease is due to expire, at least 30 days prior

to the date on which the	Landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease.
Annual Operating Expenses	Included in Annual Base Rent
Broker	Landlord and Tenant each warrant that in connection with this lease of the Premises, they have not employed or dealt with any broker, agent or finder.
Legal Fees	Tenant's shall be solely responsible for all legal fees associated with the preparation of this Letter of Intent and all additional lease documents prepared for the Premises. Tenant acknowledges and accepts that Landlord has entered into a similar Letter of Intent, as well as a Lease Agreement with another entity ("Initial Entity") for the identical purpose as stated in the Use of Premises section of this Letter of Intent to Lease. Said Lease Agreement is contingent upon the Initial Entity's ability to secure the required approvals and licenses to conduct such use in New York. If the Initial Entity does secure such approvals and licenses, Tenant agrees that its contingent lease with Landlord will immediately become null and void, without cost or penalty to Landlord.

Landlord shall prepare a draft of the Lease and deliver it to Tenant's attorney promptly after execution hereof. The foregoing provisions of this Letter of Intent shall be non-binding upon the parties: however, the parties shall negotiate diligently and in good faith in an effort to agree on the Lease based upon the terms of this letter of intent. Upon execution of the Lease, this letter of intent shall be merged therein.

LANDLORD:

By: T. Gordon F.

Date: 6/3/15

TENANT: Kinex Supportive Pharmaceuticals, LLC

By:
Tom Miller

Date: 5/20/2015

LETTER OF INTENT TO LEASE

May 19, 2015

Location:	Upstate Insulated Glass Building 2320 Court Street Syracuse, New York 13206
Landlord:	James Markert 2320 Court Street Syracuse, NY 13206
Tenant:	Kinex Supportive Pharmaceuticals, LLC c/o Kinex Pharmaceuticals, Inc. 701 Ellicott Street Buffalo, NY 14203
Premises:	Location, consisting of Approx. 800sq. ft.
Commencement Date:	To be determined but not later than August 1, 2015.
Term and Gross Rental Rate:	Five (5) year term - $10.00/sf plus Utilities (Gas & Electric) Ten (10) year term - $9.50/sf plus Utilities (Gas & Electric)
Rental Rate Annual Increase:	Three percent (3%) per year of base rental rate
Security Deposit:	$667.00
Use of Premises:	Retail Space for dispensing of medical marijuana.
Landlord Work:	N/A
Tenant Work:	Tenant improvements to be done in accordance with the plans provided by Architect, to be mutually agreed upon by Landlord and Tenant. Tenant to be responsible for cost of all build outs and improvements. Landlord and Tenant to agree upon a commercially reasonable bailout plan prior to execution of lease.
Additional Matters:	Landlord acknowledges the following is legally required of Tenant by New York State. The definitive lease will provide (a) that Landlord's rights of reentry into the Premises will prohibit Landlord from manufacturing and/or dispensing medical marihuana on the Premises in accordance with Article 33 of the Public Health Law and (b) Landlord will provide the New York State Department of Health, Mayor Erastus Corning 2nd Tower, The Governor Nelson A. Rockefeller 29 Empire State Plaza, Albany, N.Y. 12237, with notification by certified mail of its intent to reenter the Premises or to initiate dispossess proceedings or that the lease is due to expire, at least 30 days prior to the date on which the Landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease.

Annual Operating Expenses:	Pro Rata Share 17% based on 4600 SF building
Broker:	Sutton Real Estate is the only Broker involved and any commission will be payable by the Landlord and the Tenant warrants that in connection with this lease of the Premises, they have not employed or dealt with any broker, agent or finder.
Legal Fees:	Lessee shall be solely responsible for all legal fees associated with the preparation of this Letter of Intent and all additional lease documents prepared for the Premises.

Lessor's counsel shall prepare a draft of the Lease and deliver it to Lessee's attorney promptly after execution hereof. The foregoing provisions of this Letter of Intent shall be non-binding upon the parties; however, the parties shall negotiate diligently and in good faith in an effort to agree on the Lease based upon the terms of this letter of intent. Upon execution of the Lease, this letter of intent shall be merged therein.

LANDLORD:

By: _____

Date: 5/20/15

TENANT: Kinex Supportive Pharmaceuticals, LLC

By: _____

Date: 6/1/2015

LETTER OF INTENT TO LEASE

June 3, 2015

Location:	Columbia Plaza 933 New Loudon Road (US Rte 9), Latham, NY 12110
Landlord:	Nigro Companies
Tenant:	Kinex Supportive Pharmaceuticals, LLC 701 Ellicott Street Buffalo, New York 14203
Premises:	1,700 square feet, commercial retail space.
Commencement Date:	June 3, 2015
Term and Gross Rental Rate:	Location, consisting of 1,700 sq. ft. To be determined but not later than August 1, 2015
Rental Rate Annual Increase:	Three (3) year term - $__.00 psf plus electric/heat
Security Deposit:	
Use of Premises:	Three present (3%) per year of base rental rate $_____
Landlord Work:	Retail space for dispensing of medical marijuana.
Tenant Work:	Building interior renovation to meet NYS medical marijuana dispensary requirements. Tenant improvements to be done in accordance with the plans provided by Architect, to be mutually agreed upon by Landlord and Tenant. Tenant to be responsible for cost of all build outs and improvements. Landlord and Tenant to agree upon a commercially reasonable bailout plan prior to execution of lease.
Internet Accessibility	Yes _X_ No___ Service Provider: Verizon
Additional Matters:	Landlord acknowledges the following is legally required of Tenant by New York State. The definitive lease will provide (a) that Landlord's rights of reentry into the Premises will prohibit Landlord from manufacturing and/or dispensing medical marijuana on the Premises in accordance with Article 33 of Public Health Law and (b) Landlord will provide the New York State Department of health, Mayor Erastus Corning 2nd Tower, The Governor Nelson A. Rockefeller 29 Empire State Plaza, Albany, N.Y. 12237. with notification by certified mail of its

	intent to reenter the Premises or to initiate dispossess proceeding or that the lease is due to expire, at least 30 days prior to the date on which the Landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease.
Annual Operating Expenses	TBD
Broker	Landlord and Tenant each warrant that in connection with this lease of the Premises, they have not employed or dealt with any broker, agent or finder.
Legal Fees	Lessee shall be solely responsible for all legal fees associated with the preparation of this letter of Intent and all additional lease documents prepared for the Premises.

Lessor's counsel shall prepare a draft of the Lease and deliver it to Lessee's attorney promptly after execution hereof. The foregoing provisions of this Letter of Intent shall be non-binding upon the parties; however, the parties shall negotiate diligently and in good faith in an effort to agree on the Lease based upon the terms of this letter of intent. Upon execution of the Lease, this letter of intent shall be merged therein.

LANDLORD:

By: _____

Date: 5/25/2015

TENANT: Kinex Supportive Pharmaceuticals, LLC

By: _____

Date: 6/1/2015

To Kinex Supportive Pharmaceuticals,

The location of 135 Corporate Woods in Rochester NY 14623 has internet access with speeds ranging from up to 7/1M to up to 15/2M.

Tammy Bonham
Sales & Service Representative, Commercial Contact Center
Frontier Communications
100 CTE Drive
Dallas, PA 18612
877-433-3806, ex [redacted]
Fax 585-262-9693

tammy.bonham@ftr.com

John J. Wolf

[redacted]

OBJECTIVE: To obtain a Criminal Investigator position in a professional environment in which I will progressively utilize my extensive criminal justice educational background and experience.

RELEVANT SKILLS: Twenty five years of experience in the criminal justice field working with the New York State Police. Extensive knowledge of laws, legal codes, court procedures, government regulations and agency rules. Excellent communication and interpersonal skills.

EDUCATION: **Buffalo State College,** Buffalo, New York
Completed three years of Criminal Justice Program, 1988

CERTIFIED EXPERIENCE: **New York State Police, September 18, 1988- July 17, 2013**

September 1988 - August 2001 - Trooper

- Enforce vehicle and traffic laws.
- Respond to calls for service that include domestic incidents, missing children, assaults, burglaries, robberies, and homicides.
- Reconstruction of fatal and serious personal injury automobile accidents.
- Forensically process crime scenes.

August 2001 – April 2004 – Promoted to rank of Investigator – Bureau of Criminal Investigation

- Investigate major criminal cases that include but are not limited to homicides, sexual crimes, identity theft, fatal motor vehicle accidents, all death related, weapons, drugs, fraud, burglary, gaming and forgery.
- Conduct multi-agency investigations that occur throughout several jurisdictions.
- Obtained and verified evidence by interviewing and observing suspects and witnesses.
- Maintain relationships with law enforcement agencies.

February 2002 – Promoted to rank of Sergeant

- Supervise the work of members and employees assigned to the station.
- Instructed members in the proper discharge of duties.
- Review and approve administrative paperwork.

April 2004 – July 2013 – Promoted to rank of Senior Investigator

- Responsible for supervising and maintaining several individual investigators and their daily job duties.
- Oversight of felony criminal cases.
- Administrative duties including but not limited to scheduling, review of paperwork, and preparing reports that detail investigation findings.

Additional Training

- State Police Basic Academy
- Field Training Officer
- Crime Scene Technician
- Hank Williams Homicide Seminar

AWARDS: **New York State Police**

- 2003 Investigator of the Year
- 2007 Senior Investigator of the Year
- 2011 Senior Investigator of the Year

REFERENCES: Excellent personal and professional references available at your request.

ROBERT F. KEEM

SUMMARY

- Effective leader in organization and proficient in managing multiple personnel levels.
- Team player, work well with management, customers, suppliers and operation personnel.
- Excellent communication and problem solving skills within department and in multidisciplinary environment.
- Led productivity projects to reduce cost and improve efficiency
- 15+ years of experience in Quality Assurance and Validation.
- Investigation and resolution for deviations/variances and CAPA closure.
- Experience in pharmaceutical, medical device and biotech production environment.
- Willing to travel.

Quality Assurance proficiencies include the following subject areas:

- Trained and led team members on Quality Management System policies and procedures.
- Proficient in execution of compliance to 15013485 and cGMPs (820)
- Trained auditor – internal , external and site host
- Investigation and root cause analysis
- Metric development, establishing appropriate goal, measurement intervals, and use in management reviews
- Perform gap analysis and implementation of quality management systems
- Developing supplier management programs based on risk
- Developing new capabilities within organization (e.g., stability program)

Validation proficiencies include the following subject areas:

- Proficient in generating and executing of all validation documents, including Validation Plan, Gap Analysis, Remediation Plan, URS, FRS, FAT, PFMEA, Risk Assessment, Design Specifications, IQ, OQ, and PQ Test Protocols, Traceability Matrices, Test Method Validation, Standard Operating Procedures (SOPs), and Validation Summary Reports.
- Ensured project documentation complied with internal policies and procedures, and external regulations.
- Proficient in equipment, assay and process validation

SKILLS

Life Sciences:	ISO Quality System Regulation, FDA Quality System Regulation, Validation Life Cycle Methodologies, cGMP/GLP Audits, Gap Analysis, SOP Development, FDA Compliance for 21 CFR Part 11, 58, 210, 211 and 820
Hardware:	HPLC, UPLC, GC, various laboratory instruments
Software:	Microsoft applications (Microsoft Office, Microsoft Windows, etc.), Trackwise, Agile, Compliance Wire

Robert F. Keem
[redacted]

Redacted pursuant to N.Y. Public Officers Law, Art.6

Redacted pursuant to N.Y. Public Officers Law, Art.6

- Participated on investigation teams and helped trouble shoot product failures; including out of specification investigations
- Interaction with technical services and manufacturing for on-time release of finished goods

LIFE TECHOLOGIES INC., GRAND ISLAND, NY — December 1997 – March 2001

Staff Scientist: Research and Development

- Managed Media Analytical Services Laboratory including supervision of associate scientists
- Coordinated testing and review of spent media analysis for mammalian cell culture
- Project management, assay development (HPLC, GC, spectrophotometric and enzymatic assays)
- Writing and completion of software and instrument validations
- SOP and report generation
- Instrument maintenance and trouble shooting
- Quality Assurance
- Development of specifications for finished products (Cell Culture Media and Reagents)
- Trouble shooting of out of specification and product failures

CLINCAL PHARMOCOKINETICS LABORATORY, MILLARD FILLMORE HEALTH SYSTEM, BUFFALO, NY — June 1995 - December 1997

Research Scientist: Analytical Division

- Direct supervision of Laboratory Technologists and Technicians
- Oversee Pharm.0. research projects.
- Managed the development, implemented and application of analytical methods for drug analysis and metabolites in biological specimens
- Project management, assay development (HPLC, UV, enzyme), computer templates design and Validation, SOP and report generation, instrument maintenance
- Quality assurance.

June 1990 - February 1993

LYPHOMED, INC., DIVISION OF FUJISAWA, USA, GRAND ISLAND, NY

Scientist: Quality Control

- Developed, implemented and validated assay and test methodologies for all new products manufactured
- Coordinated manufacturing of new R&D experimental products
- Calibration and maintenance of instrumentation
- Training of new personnel

AWARDS

Robert F. Keem
[redacted]

[redacted]

Exhibits

- Hejmanowski LB, Keem RF, Adams MH, Longsteth J, and Wilton JH. Determination of Free Oxaprozin Plasma Concentrations by Ultrafiltrati on. American Association of Pharmaceutical Scientist Or1ando Florida, October 1993.

- Hejmanowski LB, Keem RF, Doell JM, and Wilton JH. Determination of Unchanged Hydralazine in Human Whole Blood. American Association of Pharmaceutical Scientists Boston, Massachusetts, October 1997 Chemistry

- Keem RF, Godwin, Fike, Gorfien and Price. Analysis of Factors Affecting Cell Growth and Protein Expression in Eukaryotic Cell Culture Systems. American Chemical Society National Meeting, Boston, Massachusetts, August 1998 Chemistry

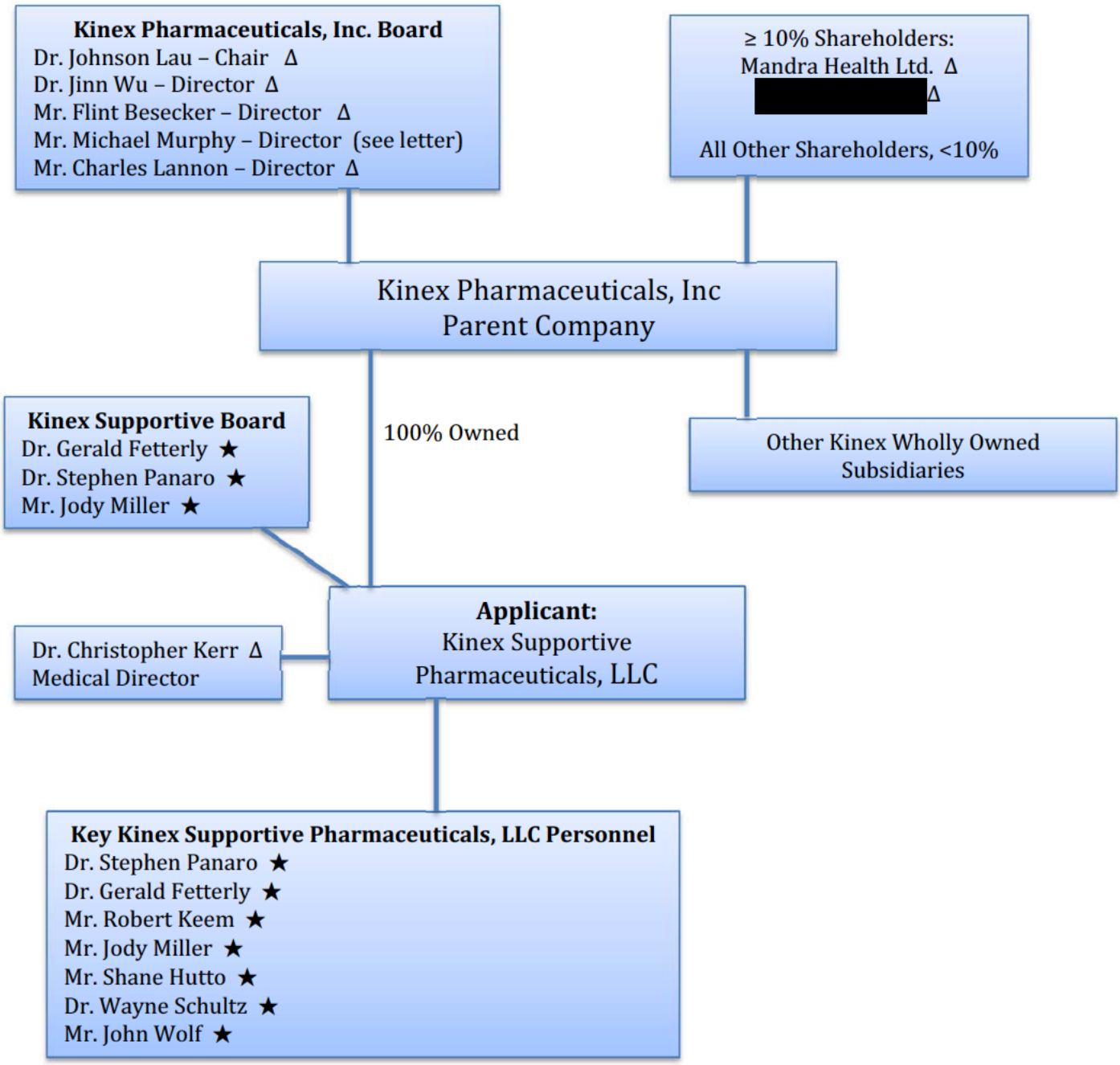
- Keem RF, Analysis of Cholesterol in Mammalian Cell Culture Products and Supplements, American Association of Pharmaceuticals Scientists, Indiana October 2000

EDUCATION

B.S. Buffalo State College, State University of New York, Chemistry
M.A. Buffalo State College, State University of New York, Analytical Chemistry

References furnished upon request

Robert F. Keem
[redacted]



★ Finger Print, Background Check and Affidavit

Δ Affidavit Only

Kinex Supportive Pharmaceuticals, LLC
Attachment G

05/18/2015	American PACE Exchange, LLC	Engagement services through 4/30/15 related to start up	5,606.25
05/21/2015	REAL Property Managment Greater Buffalo	Service to locate land to be used for project	3,500.00
05/22/2015	Architectural Resources	Architectural Schematic Design	53,000.00
05/22/2015	Lange	Lighting Design	30,000.00
05/22/2015	Concept Construction Corp	Construction agreement	5,000.00
05/22/2015	Upstate Consultants LLC	Start up costs	4,000.00
05/28/2015	Woods Oviatt Gilman LLP	Filing fees	210.00
05/28/2015	Woods Oviatt Gilman LLP	Legal fees related to NYS DOH application	12,500.00
05/28/2015	Nixon Peabody	Legal startup costs	15,000.00
05/28/2015	John Wolf	Secutiry Design	2,000.00
05/28/2015	TINAD	Dispensary Design	15,000.00
06/01/2015	Philadelphia Surety	Bond	50,000.00
06/01/2015	NYS DOH	Application filing fee	10,000.00
06/01/2015	NYS DOH	Application fee	200,000.00
06/05/2015	American PACE Exchange, LLC	Engagement services through 6/05/15	28,075.00
			$ 433,891.25

Local 338

JOHN R. DURSO
President

JOSEPH FONTANO
Secretary-Treasurer

RWDSU/UFCW

JACK CAFFEY JR.
Executive Vice President

DEBRA BOLLBACH
Recorder

Howard Zucker
Commissioner
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, New York 12237

June 1, 2015

Re: Labor Peace Agreement between Local 338, RWDSU/UFCW and Kinex Supportive Pharmaceuticals, LLC

Dear Commissioner Zucker,

Local 338, RWDSU/UFCW ("Local 338") is a labor organization, as defined in 29 U.S.C. § 402(i) and 29 U.S.C. § 152(5), representing close to 20,000 employees in New York State and its environs.

The enclosed document entitled, Neutrality Agreement, is intended in part to satisfy and comply with the requirement, under the New York Public Health Law, that an applicant (Kinex Supportive Pharmaceuticals, LLC) seeking a license to conduct business relating to the use of medical marijuana in New York State submit proof that it has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. See Public Health Law §§ 3360(14), 3365(1)(III), 3365(3)(VII), 3365(6)(IV), and 3365(7).

The Neutrality Agreement contains explicit language which protects the State's proprietary interests by prohibiting Local 338 from engaging in picketing, work stoppages, boycotts, and any other economic interference with the business of an entity licensed to engage in the business relating to the use of medical marijuana in New York State.

Should any changes in the Neutrality Agreement be necessary for an applicant to comply with the Public Health Law, please feel free to communicate with us directly.

Thank you for your consideration.

Sincerely,

Joseph Fontano
Secretary-Treasurer

LABOR PEACE / NEUTRALITY AGREEMENT
BY AND BETWEEN
KINEX SUPPORTIVE PHARMACEUTICALS, LLC
AND
LOCAL 338, RWDSU/UFCW

By this Agreement dated June 1, 2015, Kinex Supportive Pharmaceuticals, LLC (the "Employer") and Local 338, RWDSU/UFCW, 1505 Kellum Place, Mineola, New York (the "Union") hereby establish the following procedure to address the Union's efforts to organize employees in any existing or new facility owned or operated by the Employer in which the employees are not represented by a labor organization:

1. The term, "employees," used herein shall include all full time and part-time employees, including, but not limited to, pharmacists, pharmacy technicians, dispensaries, drivers, growers, retail, manufacturers, trimmers, and anyone else performing work for or on behalf of the Employer, and shall exclude only who are statutorily excluded by the National Labor Relations Act ("NLRA"). This Agreement shall not apply to any other parent, subsidiary or affiliate of the Employer.

2. Within ten (10) days after receiving written notice of the Union's intent, the Employer agrees to furnish the Union with a complete list of employees in the shop designated in the notice, including job classifications, departments, street addresses, telephone numbers and e-mail addresses. The Employer agrees to thereafter provide updated lists as reasonably requested. The Employer waives the right under the NLRA to file any petition with the National Labor Relations Board for any election in connection with the invocation of this Agreement and agrees to refrain from directly or indirectly supporting any such petition.

3. The Employer agrees to take a neutral approach to unionization of employees. Neutrality means that the Employer will neither help nor hinder the Union's organizing effort by, for example, directly or indirectly demeaning by word or deed the Union or its representatives, or directly or indirectly supporting or assisting in any way any person or group who may oppose the Union. The Employer agrees not to communicate to any employee that it disfavors the Union or the signing of authorization cards, or that they may suffer adverse consequences for supporting the Union or signing cards. The Employer also agrees that it, and its managers, supervisors and other representatives will refer to the Union by name and not as "third party," "outsider" or in similar manner. The parties will conduct themselves with mutual respect for each other during any organizing effort.

4. During organizing efforts, the Employer's managers, supervisors and other representatives will remain neutral and will refrain from communicating with employees about how they should respond to the Union. The Employer agrees to inform all of its managers, supervisors and representatives of this obligation and that the Employer has no objection to employees supporting the Union or engaging in union activities, including meeting with Union representatives or signing authorization cards. The Employer will promptly terminate any violation of this provision and immediately act to discourage any additional violation, including disciplining any manager' or supervisor - or terminating its relationship with any independent

contractor representative - who violates it. The Employer agrees to take prompt action to mitigate the effects of any violation, including informing employees of the Employer's position on organizing and the rights of employees to organize.

5. The Employer agrees to permit Union representatives access to the workplace to communicate with employees, including through the distribution of materials. Union representatives will not disrupt the Employer's operations or unreasonably interfere with employee production.

6. The facility's highest level manager will meet with and tell employees that the Employer has no objection to employees meeting with Union representatives, supporting the Union or signing authorization cards. That manager will also tell employees that the Employer is neutral in their selection of union representation.

7. If the Union provides evidence in support of its claim that a majority of employees have designated the Union as their collective bargaining representative, the Employer will recognize the Union as such representative of the employees in the bargaining unit described in the Union's notice invoking this provision and will extend this Agreement to them.

8. If both the Union and the Employer mutually agree that additional Agreement provisions are necessary for the new unit or if the National Labor Relations Board or a court determines that the parties may not lawfully extend this Agreement to the unit, the parties agree to bargain in good faith over a collective bargaining agreement to cover the employees. The parties agree to commence bargaining within 20 business days from the date the neutral verifies the Union's majority. If they are unable to agree to an initial collective bargaining agreement, the parties agree to submit all open provisions and issues regarding the initial collective bargaining agreement to final and binding interest arbitration. If they are unable to select an arbitrator, the parties shall select an arbitrator to set the open provisions and resolve any other issues in accordance with the procedures of this Agreement's arbitration provision.

9. The parties agree to resolve any dispute over the interpretation of this provision through expedited arbitration. The parties will invoke expedited arbitration by requesting an arbitrators list from the American Arbitration Association. Within 10 days of receiving AAA's arbitrators' list, the parties will submit their struck lists to the AAA. The parties agree that AAA will follow its labor arbitration rules to select an arbitrator based on the list or lists the parties submit. The AAA will strictly apply its rule requiring struck lists to be timely submitted in accordance with this provision. The arbitrator will hear the dispute on either the first or second date the arbitrator is available and issue an award within 20 days thereafter. The parties will equally share the arbitrator's fees and costs.

10. The parties agree that the arbitrator has the authority to direct the breaching party to specifically perform its obligations under this provision. The arbitrator may award a penalty of up to $10,000 for willful breaches. A willful breach is one that clearly violated this provision and was not corrected after the aggrieved party provided notice of it to the violating party. The parties consent to the entry of the arbitrator's award as the order of judgment of a United States District Court, without notice.

11. The Union and the Employer recognize that this Agreement is in their mutual best interests and therefore agree to prevent evasion of the terms of this Agreement through the use of contractors and/or subcontractors. To comply with the spirit of this Agreement, the Employer shall, as a condition of its relationship with any contractor and/or subcontractor that is providing any of the services described in Section 1 above require that: (a) the contractor and/or subcontractor enter into a neutrality agreement with the Union; and (b) immediately notify the Union when seeking to form a business relationship with the contractor and/or subcontractor.

12. Labor Peace Agreement: In the event that the Union attempts to organize the Employer's employees or actually represents the Employer's employees at any particular location, then the Union hereby promises that it will not at any time covered by this agreement engage in any picketing, work stoppages, boycotts or any other economic interference with the Employer's business at that location, provided the employer has not violated any of the terms of this agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed this 1st day of June 2015, by their duly authorized representatives.

LOCAL 338, RWSDU/UFCW

By: _____

Date: 6/1/15

Name: Joseph Fontano

Title: Secretary-Treasurer

Witness:

Kinex Supportive Pharmaceuticals, LLC

By: _____

Date: 06/02/15

Name: Stephen A. Panaro

Title: President + CEO

Witness: Christian J. Henrich, Esq.
716.248.3211

65 Franklin Street, Room 601
Buffalo, New York 14202

Kinex Supportive Pharmaceuticals,

In order to comply with the Compassionate Care Act application, proof of internet access from a local service provider is needed. More specifically, attachment K calls for proof that all applicants' manufacturing and dispensing facilities are located in an area with internet connectivity. For the dispensary location at 81 Benbro Dr, Cheektowaga, NY 14225. Verizon has services HSI & Hicap services available in the area [HSI is High Speed Internet (DSL) - up to 3Mb, hicap services – DS1, DS3, Ethernet].

Sincerely,

James J. Murphy

James J. Murphy
OSP Network Engineer – Design
65 Franklin St, Flr 6
Buffalo, NY 14202

O: (716) 840-8698

KINEX SUPPORTIVE PHARMACEUTICALS, LLC
OPERATING AGREEMENT

THIS OPERATING AGREEMENT is entered into as of the 26th day of May, 2015, by **Kinex Pharmaceuticals, Inc.** (the "**Member**").

A. The Member desires to organize a limited liability company pursuant to New York law and establish terms and conditions relating to its organization and governance as set forth in this Operating Agreement.

NOW THEREFORE, the Member establishes the following:

ARTICLE I
DEFINITIONS

1.01 Act. The New York Limited Liability Company Law and any successor statute, as amended from time to time.

1.02 Agreement. This Kinex Supportive Pharmaceuticals, LLC Operating Agreement, as amended from time to time.

1.03 Articles of Organization or Articles. The Articles of Organization filed for the Company in accordance with the Act.

1.04 Code. The Internal Revenue Code of 1986, as amended.

1.05 Company. Kinex Supportive Pharmaceuticals, LLC.

1.06 Company Property. Any such real or personal property as may be acquired by the Company.

1.07 Membership Interest or Interest. The Interest of the Member in the Company, including the right to any and all benefits to which such Member may be entitled in accordance with this Agreement, and the obligations as provided in this Agreement and the Act.

ARTICLE II
FORMATION, PURPOSE AND POWERS OF THE COMPANY

2.01 Formation. The Company has been formed as a limited liability company pursuant to the provisions of the Act. The Member shall take all such further action and file such additional instruments as shall be necessary or appropriate to conduct business in any jurisdiction where assets of the Company are located.

2.02 Principal Office of the Company. The principal office of the Company shall be 701 Ellicott Street, Buffalo, NY 14203, or at such other place or places as the Member may designate.

2.03 Purpose. The business of the Company is to grow and sell marijuana, for medicinal purposes only, in the State of New York pursuant applicable New York law and

conduct any other business reasonably related to the foregoing.

2.04 Recapitalization, Acquisitions, Restructuring and Mergers. The Company may participate in or be a party to any recapitalization, acquisition, restructuring or merger in accordance with and as allowed by the Act.

2.05 Name. The Company shall conduct business under the name Kinex Supportive Pharmaceuticals, LLC, or such other names as the Member may designate.

ARTICLE III
CAPITAL AND MEMBERSHIP INTEREST

3.00 Capital and Membership Interest. The Member owns the only membership interests of the Company and has contributed all of the Company's capital.

ARTICLE IV
TAX EFFECTS OF THE COMPANY

4.00 Tax Effects. For purposes of the Code, but only for such purposes, the Company shall be disregarded as an entity and all net profits and losses shall be computed as if the Company were a sole proprietorship. All net profits and losses and every item of income, deduction, gain, loss and credit shall be reported on the federal income tax return, Form 1120 of the Member. Notwithstanding this provision and the fact that the Company will not be considered an entity for tax purposes, the Company shall continue to be a limited liability company pursuant to the Act and provide the Member with limited liability and all other benefits available under the Act.

ARTICLE V
MANAGEMENT

5.01 Board of Manager.

(a) *Number*. The number of Managers constituting the full Board shall be not less than three (3) nor more than five (5). Initially, the full Board shall be comprised of three (3) Managers. Any change in the specific number of Managers that constitutes the full Board may only be changed by the Member. The initial Managers and members of the Board shall be Dr. Stephen Panaro, Mr. Jody Miller, and Dr. Gerald Fetterly

(b) *Election*. The Member shall elect the Managers.

(c) *Term*. Upon being elected, Managers shall serve until the earlier of their resignation, death or removal by the Member.

(d) *Qualifications*. A Manager may, but need not be, a Member.

(e) *Resignation.* Any Manager may resign at any time by giving notice to the Board. The resignation of any Manager will take effect upon receipt of that notice or at such later time as specified in the notice. Unless otherwise specified in the notice, the acceptance of the resignation will not be necessary to make it effective. The resignation of a Manager who is also a Member will not affect such Member's rights as a Member and will not constitute a withdrawal from the Company.

(f) *Removal.* Any Manager may be removed at any time, with or without cause, by the Member. The removal of a Manager who is also a Member will not, by itself, affect such Member's rights as a Member.

(g) *Vacancies.* Vacancies created by the death, resignation or removal of a Manager shall be filled by the Member, in accordance with Section 5.01(b).

(h) *Power and Authority.* Without limiting the generality of this Section 5.01, but subject to the express limitations set forth in this Agreement, all decisions with respect to the management and operations of the Company rest with the Board, and the Board shall be deemed a single manager of the Company for all purposes under the Act. With respect to any matter requiring a Member vote other than the election of Managers, the approval of the Board shall first be required. Except as otherwise expressly provided in this Agreement, or as otherwise required by law, the Member does not have any control or vote with respect to the management or operations of the Company.

5.02 Board Meetings.

(a) *Notice and Conduct of Meetings.* Meetings of the Board may be called by any Manager. All meetings will be held upon at least 24 hours' notice, except as provided below. A notice need not specify the purpose of any meeting. Notice of a meeting need not be given to any Manager who signs a waiver of notice or a consent to holding the meeting or an approval of the minutes thereof, whether before or after the meeting, or who attends the meeting without protesting, prior to its commencement, the lack of notice to such Manager. All such waivers, consents and approvals will be filed with the Company records or made a part of the minutes of the meeting. Meetings of the Board may be held at any place which has been designated in the notice of the meeting or at such place as may be approved by the Board. Managers may participate in a meeting through use of conference telephone or similar communications equipment, so long as all Managers participating in such meeting can hear one another. Participation in a meeting in such manner constitutes a presence in person at such meeting.

(b) *Committees.* The Board may create committees of the Board consisting of Managers, including an Audit Committee and Compensation Committee, with such authority and power as may be determined by the Board.

(c) *Quorum.* No action by the Board may be taken at a meeting unless a quorum of the Managers is present. A quorum of the Board shall be a majority of the full Board.

(d) *Majority Vote.* Each Manager will be entitled to one (1) vote on all matters submitted to a vote of the Board. Every act or decision done or made by a majority of the Managers at a meeting with a quorum present will be the act of the Board.

(e) *No Meetings Required.* The provisions of this Section 5.02 govern meetings of the Board if the Board elects, in its discretion, to hold meetings. However, nothing in this Agreement is intended to require that meetings of the Board be held.

(e) *Action Without a Meeting.* Any action required or permitted to be taken by the Board may be taken by the Managers without a meeting, if all of the Managers individually or collectively consent in writing to such action. Such action by written consent will have the same force and effect as a vote at a meeting of the Managers.

5.03 Officers; Additional Managers.

(a) The Board may designate and appoint officers (each, and "**Officer**") and delegate duties to such Officers from time to time in its discretion, and the extent allowable under the Act. Each Officer shall be deemed a manager (each, an "**Additional Manager**") of the Company for all purposes under the Act, with duties and authority limited to those expressly granted by the Board. All Officers serve at the discretion of, and may be removed at any time with or without cause by, the Board. The Board shall determine the compensation of any Officers unless otherwise expressly provided in this Agreement.

(b) The Company's Officers consist of a (i) Chief Executive Officer, who initially shall be Stephen Panaro, (ii) Chief Operating Officer who initially shall be Jody Miller, and (iii) a Director of Clinical Pharmacology and Regulatory Affairs who initially shall be Dr. Gerald Fetterly.

5.04 Company Tax Matters. The Board shall make any and all elections for federal, state, local, and foreign tax purposes including, without limitation, any election, if permitted by applicable law: (a) to adjust the basis of property pursuant to Sections 754, 734(b) and 743(b) of the Code, or comparable provisions of state, local, or foreign law, in connection with transfers of Units and Distributions; (b) with the consent of the Member, to extend the statute of limitations for assessment of tax deficiencies against the Member with respect to adjustments to the Company's federal, state, local, or foreign tax returns; and (c) to the extent provided in Sections 6221 through 6231 of the Code and similar provisions of federal, state, local, or foreign law, to represent the Company and the Member before taxing authorities or courts of competent jurisdiction in tax matters affecting the Company or the Member in its capacity as a Member, and to file any tax returns and execute any agreements or other documents relating to or affecting such tax matters, including agreements or other documents that bind the Member with respect to such tax matters or otherwise affect the rights of the Company and the Member.

5.05 Expenses. All expenses incurred by the Board or Officers, or any of them, in connection with the management and operation of the Company business shall be borne by the Company, and reimbursed to such person upon the presentation of proper documentation substantiating the expenses.

5.06 Liability and Indemnification of Managers and Officers.

(a) No Manager or Officer in their capacity as such shall be personally liable for any of the debts of the Company or any of the losses.

(b) A Manager or Officer of the Company shall have no personal liability to

the Company or its Member for monetary damages for breach of fiduciary duty as a Manager, or Officer, except: (i) for any breach of a duty of loyalty to the Company or its Member; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of the law; or (iii) for any transaction from which such Manager or Officer derived an improper personal benefit. By virtue of this paragraph the liability of a Manager or Officer of the Company shall be eliminated or limited to the fullest extent permitted by law, as so enacted, or by decisional law.

(c) The Company shall indemnify to the fullest extent now or hereafter permitted by law as the same exists or may hereafter be amended, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, investigation, suit, or proceeding (each, a "Proceeding"), whether civil, criminal, administrative or investigative (including, without limitation, an action by or in the right of the Company), by reason of the fact that such person is or was a Manager or Officer of the Company, or is or was serving at the request of the Company as a Manager or Officer of another Company, partnership, joint venture, trust or other enterprise, against any liability, expenses (including reasonable attorneys' fees and disbursements), loss, judgments, fines (including excise taxes and penalties) and amounts paid in settlement actually and reasonably incurred or suffered by such person in connection with such action, investigation, suit or proceeding (a) if the person to be indemnified acted in good faith and in a manner that such person reasonably believed to be in the best interest of the Company, and (b) if such action, investigation, suit, or proceeding (or part thereof) was initiated by the person to be indemnified, only if such action, investigation, suit, or proceeding was authorized in advance by the Board. Such indemnification is not exclusive of any other right to indemnification provided by law or otherwise.

(d) Except as limited by law or the provisions of this Article V, expenses incurred by an Officer or Manager in defending any Proceeding, including a Proceeding by or in the right of the Company, shall be paid by the Company to the Officer or Manager in advance of final disposition of the Proceeding. The Company may require that such Officer or Manager execute a written undertaking to repay the amount of any advance if such person is determined pursuant to this Article 5 or adjudicated to be ineligible for indemnification. Any such undertaking shall be an unlimited general obligation of the person providing same, need not be secured and may be accepted without regard to the financial ability of the person to make repayment. No advance payment of expenses shall be made if it is reasonably determined on the basis of the circumstances known at the time (without further investigation) that the Officer or Manage is ineligible for indemnification.

(e) Any repeal or modification of Section 5.06 shall not adversely affect any right or protection of any person thereunder with respect to any act or omission occurring prior to or at the time of such repeal or modification.

5.07 Key Man Insurance. The Company may establish and maintain a key man life insurance policy on any Managers and Officers as determined by the Board and in amounts as determined by the Board. Each Manager and Officer hereby consents to the issuance of any such policy and agrees to fully cooperate with the Company in obtaining any policy that the Board may determine is required.

ARTICLE VI
DISSOLUTION AND TERMINATION

6.00 Dissolution.

(a) The Company shall be dissolved and its business wound up, in the sole discretion of the Member.

(b) Upon dissolution, the Company shall be terminated, and its assets liquidated and its affairs wound up as promptly as practicable.

ARTICLE VII
MISCELLANEOUS

7.01 Partial Invalidity. In the event that any provision of this Agreement shall be held to be invalid, the same shall not affect in any respect whatsoever the validity of the remainder of this Agreement.

7.02 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

7.03 No Third Party Beneficiary. None of the provisions of this Agreement shall be for the benefit of, or enforceable by, any creditor of the Company.

The Member of this Agreement has executed this Operating Agreement as of the day and year first above written.

MEMBER

KINEX PHARMACEUTICALS, INC.

By: _____
Name: Flint D. Besecker
Title: Chief Operating Officer

JODY L. MILLER, MBA

[redacted]

EXPERIENCE:

4/13-Present **4Front Consulting Group, Inc.** Buffalo, NY
FOUNDING PARTNER: A consulting group focused on the Design / Build of specialty pharmacies, and Pharma HUB solutions for individual clients and institutions. Design - includes developing the strategic plan including all proforma financial tools, and market readiness. Build - includes the actual deployment of 4Front consultants to implement the business plan and prepare the new owners to operate the operational asset. Currently building assets in the Grocery Chain and University Health System silos.
Additionally 4Front provides "Last Mile" channel strategy and insights to major pharma manufacturers through its relationship with Blue Fin Consulting. 4Front expertise is sought for both medical and pharmacy benefit products. Particular expertise is projecting the distribution impacts of various limited distribution strategies.

6/10-3/13 **Reliance RX**, Amherst, NY

CHIEF EXECUTIVE OFFICER/CO-FOUNDER: Responsible for the development and launching of a Specialty Pharmacy. Responsibilities include developing business plan, obtaining funding, launching the company and ensuring growth. Company has grown to 20 employees and 84m in revenue.

Sold interest in Reliance to Independent Health Corporation who was the other shareholder

4/05 – 5/10 **Johnson and Johnson** (C**ENTOCOR ORTHO BIOTEC, INC.),** Horsham, Pennsylvania

AREA BUSINESS SPECIALIST: Responsible for all aspects of the business of Remicade in both hospital and physician offices. Responsibilities included payer policy knowledge, infusion suite process development.

PAYER MARKETING - STELARA LAUNCH TEAM: Responsible for market segmentation and payer strategy to include channel development and HUB services selection

Mar 99 – Feb 2005 **MEDALLIANCE, LLC,** Buffalo, New York

MANAGING PARTNER (Owner): Responsible for growing a Healthcare Services company specializing in Physician Practice Management consulting, medical billing, and medical software sales.

Mar 98-Mar 99 **Community Physicians Network (PPMC),** Louisville, KY

REGIONAL DIRECTOR, OPERATIONS AND DEVELOPMENT: Responsible for selling physicians on the PPMC business model and integrating them into the CPN business. This company was a start up funded by the majority shareholders of Humana. This start up ran out of cash and was shut down by the investors, much like most others in this category (i.e. PHYCOR and MEDPARTNERS).

Nov 95-Mar 98 **Practice Management Associates,** Buffalo, NY

OWNER: Responsible for selling and delivering high quality medical practice consulting services.

Sep 93 – Nov 95 **Partners in Occupational Health**, Kalieda Health System, Buffalo, NY

EXECUTIVE DIRECTOR: Responsible for the start up of a new company wholly owned by the Kalieda Health System. Developed business plan and secured funding from Health system. Developed offerings of company, hired all professional and administrative staff, and sold initial contracts.

Aug 91- Sep 93 **Empire Medical Management, LTD,** Syracuse, NY

REGIONAL ADMINISTRATOR: Responsible for the management and growth of a medical services company providing Independent Medical Exams for the Legal and Insurance Industries.

Feb 88-Jun 91 **Martin Army Community Hospital,** Fort Benning, Georgia

COMMANDER MEDICAL COMPANY (Captain, MSC): Responsible for the health and welfare of 600 enlisted and officer personnel.

CHIEF, PRIMARY CARE SUPPORT BRANCH: Responsible for administrative support to emergency room, family practice residency program, and 11 primary care clinics.

EDUCATION

Canisius College	M.B.A. Business Administration (1997)
Texas State University	B.H.S. Health Care Administration (1986)
University of Texas (San Antonio)	Business and Health Sciences
St. Phillips College	A.A.S. Physical Therapy (1984)
Herkimer County Community College	A.A.S. Sports Med/Athletic Training (1982)
Numerous Military Officer Courses	1985-1995

PROFESSIONAL AFFILIATIONS

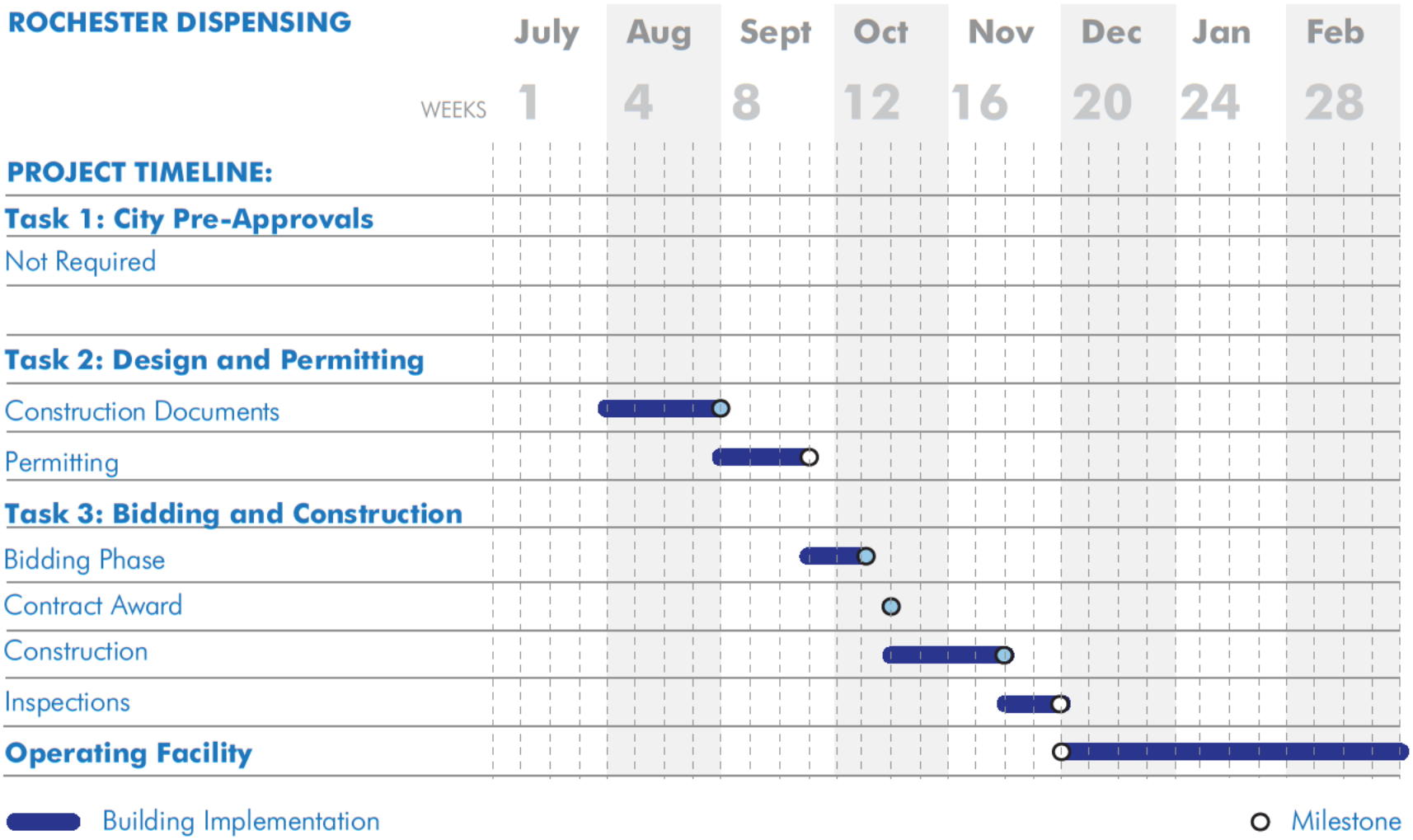
Association of Managed Care Pharmacy

LICENCES and CERTIFICATIONS

Certified Medical Practice Administrator (CMPE Inactive)
Physical Therapy Assistant (LPTA Inactive) New York
Physical Therapy Assistant (LPTA Inactive) Texas
Nursing Home Administrator (Georgia, Inactive)

PERSONAL INFORMATION

[redacted]
Served 7 years in U.S. Army, Captain, Medical Service Corp


ROCHESTER DISPENSING
July
Aug
Sept
Oct
Nov
Dec
Jan
Feb
WEEKS
1
4
8
12
16
20
24
28
PROJECT TIMELINE:
Task 1: City Pre-Approvals
Not Required
Task 2: Design and Permitting
Construction Documents
Permitting
Task 3: Bidding and Construction
Bidding Phase
Contract Award
Construction
Inspections
Operating Facility
Building Implementation
Milestone

Appendix B: Architectural Program

A SEPARATE "APPENDIX B" SHALL BE COMPLETED FOR EACH SEPARATE BUILDING AND/OR FACILITY INCLUDED IN THE ORGANIZATION'S BUSINESS PLAN

COMPANY INFORMATION	
Business Name:	Kinex Supportive Pharmaceuticals
Facility Type:	Manufacturing Facility ☐ Dispensing Facility ☑
Use and Occupancy Classification:	Mechantile
Building Construction Type and Classification:	IIb
Facility Address:	26 Corporate Woods, Rochester NY 14623
Primary Contact Telephone number:	Jody Miller, MBA (716)440-0192
Primary Contact Fax number:	

PART I – ARCHITECTURAL PROGRAM & CONSTRUCTION TIMELINE:
Applicant shall identify planning requirements, including but not limited to:

☐	TOWN BOARD APPROVAL
☐	PLANNING BOARD APPROVAL
☐	ZONING BOARD OF APPEALS APPROVAL
☑	PREPARATION OF CONSTRUCTION DOCUMENTS
☑	BUILDING PERMIT
☑	BIDDING PHASE
☑	CONTRACT AWARD PHASE PER EACH APPLICABLE CONTRACTOR (Identify all that apply)
☑	COMMENCEMENT OF CONSTRUCTION
☑	COMPLETION OF CONSTRUCTION

Appendix B – Architectural Program

PART II – SITE PLAN(S)

Applicant shall provide the appropriate details for each of the following by identifying the location and dimension on the Site Plan attached to the application for each building location.

	☑ Entrance and Exits ☑ Public Parking Spaces ☑ Staff Parking Spaces ☑ Accessible Parking Spaces ☑ Accessible Route(s)	☑ Fire Lane and/or Fire Apparatus Road ☑ Percentage of Green Space ☑ Location of Emergency Power Systems ☑ Loading & Unloading ☐ Security Gates & Fences

PART III – ENERGY SOURCES & ENGINEERING SYSTEMS:

Applicant shall provide the following minimum information to outline the specifications relating to the energy sources and engineering systems of each building included in the application.

Energy Source:

☑ Natural Gas ☐ Oil ☑ Electric
☐ Solar ☐ Other _____

Engineering Systems:

☑ Heating System: Type pkg RTU, Size _____ Efficiency _____,
Ventilation Requirements per ashre standars

☑ Cooling System: Type pkg RTU, Size _____ Efficiency _____,
Ventilation Requirements per ashre standards

☑ Ventilation & Humidification Systems:
Type pkg RTU, Size _____, Efficiency _____,
Ventilation Requirements per ashre standards

☑ Electrical Distribution Available 480/277 volt

☑ Water Supply: Municipal Water Service x or Private Well Water _____

☑ Sewage: Municipal Sewer System x or Private Septic System _____

☑ Emergency Power System:
Type battery, Size varies Efficiency _____,

Appendix B – Architectural Program

PART IV – BUILDING CODE COMPLIANCE: (pages 3-13)	
CHECK ALL APPLICABLE CODES FOR THE FACILITY	
☑	2010 BUILDING CODE OF NYS
☑	2010 FIRE CODE OF NYS
☐	2010 PLUMBING CODE OF NYS
☐	2010 MECHANICAL CODE OF NYS
☐	2010 FUEL GAS CODE OF NYS
☑	2010 PROPERTY MAINTENANCE CODE OF NYS
☐	2010 ENERGY CONSERVATION CONSTRUCTION CODE OF NYS
☐	2012 IECC COMMERCIAL PROVISIONS
☑	2010 EXISTING BUILDING CODE OF NYS
☑	NEC NATIONAL ELECTRIC CODE, (Specify Applicable Version)
☐	2014 NY CITY CONSTRUCTION CODE
☐	2008 NY CITY CONSTRUCTION CODE
☐	1968 NY CITY CONSTRUCTION CODE
☑	NFPA 101-06 LIFE SAFETY CODE
☑	ICC/ANSI A117.1-03 ACCESSIBLE AND USABLE BUILDINGS AND FACILITIES
☐	OTHER

Appendix B – Architectural Program

Select Project Type: Check all that apply. Refer to the Existing Building Code for definitions.	☐ New Building ☐ Repair ☐ Alteration Level 1 ☑ Alteration Level 2	☐ Alteration Level 3 ☐ Change of Occupancy ☐ Addition ☐ Historic Building	☐ Demolition ☐ Chapter 3. Prescriptive Compliance Method ☐ Chapter 13. Performance Compliance Method
Select Work Involved: Check all that apply.	☑ General Construction ☐ Roofing ☐ Asbestos Abatement/Environmental ☐ Fire Alarm	☐ Structural ☐ Mechanical ☑ Plumbing ☑ Electrical	☑ Site Work ☐ Sprinkler ☐ Elevators ☐ Other:_____

CODE COMPLIANCE REVIEW

Applicant shall provide all applicable information in regards to the code topic and section listed below.

1. Code Compliance Review is based on the 2010 NY State Building Code for New Construction. If any other building code applies to the location or type of construction, provide applicable code and sections that most closely relates and references the code topic and information in the code sections listed below. Provide appropriate abbreviations for other applicable codes, such as: **FC:** ***Fire Code*****, PC:** ***Plumbing Code*****, MC:** ***Mechanical Code*****, FGC:** ***Fuel Gas Code*****, ECCC:** ***Energy Conservation Code.***
2. Provide the Required standard for each applicable code section. (i.e.: area, quantity, classification type, materials, hourly separation, etc.). If section does not apply, indicate one of the following with explanation: **NA:** *Not Applicable*, **NR:** *Not Required*, **NP:** *Not Permitted*
3. Provide your facilities "Actual" value for each required standard as per applicable code section.

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
1	Use & Occupancy Classification	302.1 - 312		Use & occupancy of this facility. Identify all applicable materials, class and quantities regarding Table 307.1.	M Mercantile	M Mercantile

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
2	Combustible Storage	413		All combustible storage areas and rooms, as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
3	Hazardous Materials	414		All hazardous materials stored or used as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
4	Hazardous Materials Control Areas	414.2		Provide additional information indicating number, size, materials stored, and quantity of each material.	NA	
5	Building Area & Height	501-507		Provide the building area & height Provide all calculations and cite applicable code sections for increased Building Area & Heights allowed per building code(s).	existing building, section does not apply	
6	Incidental Use Areas	508.2		Identify all Incidental Use Areas and required fire separation of occupancies on Building Plans.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
7	Mixed Occupancies	508.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
8	Nonseparated Uses	508.3.2		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
9	Separated Uses (Ratio < 1)	508.3.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
10	Construction Classification	602		Provide Construction Classification per each building included in Application.	Type IIb	Type IIb
11	Fire Resistance Rating Reqm't for Building Elements	Table 601		Provide Fire Resistance Rating per each building element as per Table 601. Identify rating & elements on Building Plans.	not required	none provided

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
12	Exterior Wall Fire-Resistance Rating	Table 602		Identify required fire resistance rating of exterior walls on Building Plan(s).	NA	
13	Exterior Fire Separation Distance	Table 602		Identify required fire separation distance of exterior walls between Buildings on Plan.	existing building, section does not apply	
14	Fire Walls	705		Provide code information and identify all applicable required Fire Wall(s) and fire resistance requirement on Building Plans.	NA	
15	Fire Barriers	706		Provide code information and identify all applicable required Fire Barrier(s) and fire resistance requirement on Building Plans.	2 hr fire barriers required between fire areas	provided in tenant seperations
16	Shaft Enclosures	707		Provide code information and identify all applicable required Shaft Wall(s) and fire resistance requirement on Building Plans.	2 hr shaft enclosures required	see plans
17	Fire Partitions	708		Provide code information and identify all applicable required Fire Partition(s) and fire resistance requirement on Building Plans.	1 hr fire partitions required	see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
18	Horizontal Assemblies	711		Provide code information and identify all applicable required Horizontal Assemblies and fire resistance requirement on Building Plans.	Not Required	
19	Fire Protection: Sprinkler System	903		Indicate Type of Sprinkler System: ☑ NFPA 13 ☐ NFPA 13 R ☐ NFPA 13D Provide code information of all applicable requirements for Automatic Sprinkler Systems with code section cited.	Not required under 12,000sqft	fire area under 12,000sqft
20	Alt. Fire Extinguishing System	904		Provide code information of all applicable requirements for Alternative Automatic Fire-Extinguishing Systems with code section(s) cited.	NA	
21	Standpipe System	905		Provide code information of all applicable requirements for Standpipe Systems with code section(s) cited.	NA	
22	Fire Alarm & Detection Systems	907		Provide code information of all applicable requirements for Fire Alarm System(s) with code section cited. Indicate Type of Fire Alarm System ☐ Addressable ☑ Hardwired (zoned)	required with occupant load over 500	occupant load is less than 500 therefore its not required

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
23	Emergency Alarm System	908		Provide code information of all applicable requirements for Emergency Alarm Systems with code section cited.	NA	
24	Fire Department Connections	912		Identify Fire Department connections in accordance with NFPA applicable standard.	NA	
25	Exits	1001.1 &2		Identify on the Building Plans and documents, per each door, the following information: door width, door height, direction of swing, type of construction, hourly rating, and door closures.	required	provided, see plans
26	Occupant Load	1004 & Table 1004.1.1		Identify the use/name of each room, dimensions of each room, and Occupant Loads per each room on the Building Plans.	total occupant load is 38	see plans for occupant loads of individual spaces
27	Egress Width	1005		Provide egress widths & cite applicable code section(s) and requirement(s) on the Building Plans	stairways .3 per occupant, other components .2	stairways 12" other 8"
28	Accessible Means of Egress	1007.1		Provide accessible means of egress as per Section 1007 & cite applicable code section(s) and requirement(s) on the Building Plans.	required	provided, see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
29	Doors, Gates, and Turnstiles	1008		Means of egress doors shall meet the requirements of this section.	required	Provided, See plans
30	Interior Stairs	1009		Identify the following information for each stairway on the Building Plan(s): the width of stairways; the height, width, depth and number of risers and treads; dimensions of landings; stairway construction type; and handrail height.	required	See plans
31	Ramps	1010.1		Identify the following information of each ramp, on the Building Plan(s): width; total vertical rise; length of ramp; and handrail height.	NA	
32	Common Path of Travel	1014.3		Identify on the Building Plan(s): the length of the "Common Path of Travel" per each room as per applicable building code requirements.	not greater than 75'	See plans
33	Exit Doorway Arrangement	1015		Identify on the Building Plan(s): applicable building code requirements for all Exits and Exit Access Doorways per each room and required exits in all buildings.	maximum occupant load with one means of egress is 49 people per space	See plans
34	Corridor Fire Rating	1017.1		Identify, on the Building Plan(s): all corridors with required fire resistance and the applicable fire rating.	1 hr fire resistance rating required in corridors	1hr provided See plans

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No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
35	Corridor Width	1017.2		Identify on the Building Plan(s): the width of all corridors. Provide applicable code section(s) and requirement(s).	44" min required	49.5" provided
36	Dead End Corridor	1017.3		Corridors shall not exceed the maximum dead end corridor length as per applicable code.	shall not exceed 20'	none provided
37	Number of Exits and Continuity	1019		Identify on the Building Plan(s): required number of exits, continuity and arrangement as per the applicable code requirements.	1 exits required	1 exit provided
38	Vertical Exit Enclosures	1020		Identify on the Building Plan(s): all applicable code requirements for each Vertical Exit Enclosure.	NA	no vertical exit enclosures
39	Exit Passageways	1021		Identify on the Building Plan(s): all applicable code requirements for each Exit Passageway.	required	Provided
40	Horizontal Exits	1022		Identify on the Building Plan(s): all applicable code requirements for each Horizontal Exit.	NA	

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No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
41	Exterior Exit Ramps & Stairways	1023		Identify on the Building Plan(s): all applicable code requirements for each exterior exit ramps and stairways.	NA	no exterior stairs or ramps are provided in the project
42	Exit Discharge	1024		Identify on the Building Plan(s): all applicable code requirements for each Exit Discharge.	required	provided, see plans
43	Accessibility	1101.1 - 1110 & ICC/A117. 1(03)		Identify on the Building Plan(s): all applicable code requirements such that the design and construction of each building/facility provides accessibility to physically disabled persons.	required	provided, see plans for door and fixture clearances
44	Energy Conservation	2010 NYS ECCC & IECC 2012		Identify the R-Value and U-Value of each construction component and assembly of the building envelope as required in the applicable energy and building code(s).	existing building, section does not apply	
45	Emergency & Standby Power	2702.1		Identify emergency & Standby Power locations and specifications of the system to be provided.	NA	
46	Smoke Control Systems	2702.2.2		Identify the Standby power for smoke control systems in accordance with Section 909.11 of NYS Building Code.	NA	

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No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
47	Plumbing Fixture Count	2902.1		Identify on the Building Plan(s): the minimum plumbing facilities as per applicable plumbing code(s).	1 DF, 1 service sink, 1 WC M, 1WC F, 1Lav M, 1Lav F	1 DF, 1 service sink, 1 WC M, 1WC F, 1Lav M, 1 Lav F
48	Available Street Water Pressure			Provide the available street or well water pressure.	existing building, TBD	
49	Fire Apparatus Access Road	FC503.1		Identify on the Site Plan: Fire Apparatus Road, Fire Lane and other Fire Service requirements per applicable Building and Fire Codes.	see site plan	see site plan

L. Wayne Schultz, Ph.D.

[redacted]

[redacted]

[redacted]

A highly trained, multidisciplinary project team leader with experience in the fields of chemistry, biochemistry, molecular biology, infectious disease, structural biology, and drug design/discovery. Successful track record of peer reviewed publications (30), invited lectures (15), and government research funding (>$7.5M). An entrepreneurial minded scientist with tech startup, business development, GMP manufacturing, and sales experience.

EXPERIENCE

Redacted pursuant to N.Y. Public Officers Law, Art. 6

EDUCATION

Cornell University, Ithaca, NY—Ph.D. Biophysical Chemistry 1995
Thesis Title: *Structural Studies of Immunophilins and Their Complexes*

Cornell University, Ithaca, NY— M.S. Analytical Chemistry 1992

College of Wooster, Wooster, OH—B.A. Chemistry 1990

SPECIFIC SCIENTIFIC EXPERIENCE

Molecular Biology, Cloning, Fermentation, Protein expression and purification, Protein crystallization, X-ray Crystallography, Fluorometry, Small-angle X-ray scattering, UV-vis and IR spectroscopy, Biochemical assay, SPR, calorimetry, ELISA, Western blotting.

AWARDS and HONORS

Semi-Finalist 43North Business Plan Competition	2014
Western New York Healthcare 50	2012
NIH Postdoctoral Fellowship, University of Wisconsin, Madison	1996-1999
Cover illustration, *Bioorg. Med. Chem. Lett.*	1998
NIH Biotechnology Training Grant Fellow, Cornell University	1991-1994
ACA Pauling Prize for Poster Presentation	1994
DuPont Outstanding Teaching Assistant Award, Cornell University	1991
Phi Beta Kappa	1990
Sigma Xi	1990
Honors Thesis/Major, College of Wooster	1990

PUBLICATIONS

30. Umland, T.C., Schultz, L.W., and Russo, T.A., Re-evaluating the approach of drug target discovery in multidrug-resistant Gram- negative bacilli. Future Microbiol. 2014; 9(10): 1113-6. Doi: 10.2217/fmb.14.72.

29. Patel, D., Schultz, L.W. and Umland, T.C., Influenza A polymerase subunit PB2 possesses overlapping binding sites for polymerase subunit PB1 and human MAVS proteins. Virus Res. 2012 Dec 12. pii: S0168-1702(12)00465-0. doi: 10.1016/j.virusres.2012.12.003.

28. Umland, T.C., Schultz, L.W., Macdonald, U., Beanan, J.M., Olson, R. and Russo, T.A., In vivo-validated essential genes identified in Acinetobacter baumannii by using human ascites overlap poorly with essential genes detected on laboratory media. MBio. Aug 31;**3(4)** (2012) pii: e00113-12. doi: 10.1128/mBio.00113-12. PMID: 22911967.

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Liu, L., Schultz, L. W. and Hastings, J. W. (2005) pH regulation of luciferase activity in dinoflagellates involves a novel enzymatic mechanism. In Bioluminescence & Chemiluminescence: (A. Tsuji, M. Maeda, L.J. Kricka, and P. E. Stanley, Eds.), World Scientific Publ., London.

Patents Held

Raines, R.T.; Leland, P.L.; Schultz, L.W., Engineered Cytotoxic Ribonuclease A, US Patent 5,840,296 (2000).

PROFESSIONAL MEMBERSHIPS AND ACTIVITIES:

Session chair, SAXS, Pittsburgh Diffraction Conference, Buffalo, NY	October, 2007
Session organizer, 32nd Annual Meeting of the American Society for Photobiology Seattle, WA	July, 2004
Chair, Buffalo-Hamilton-Toronto Crystallography Symposium, Hamilton, ON	November, 2001
Session chair, Phasing Methods Pittsburgh Diffraction Conference, Pittsburgh, PA	October, 2000
Member, American Crystallographic Association	1991-present
Member, American Association for the Advancement of Science	1993-present

Kinex Supportive Pharmaceuticals, LLC Medical Marijuana Program Application for Registration as a Registered Organization

Security Plan

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1.1 INTRODUCTION

Security for Kinex Supportive Pharmaceuticals, LLC including relevant facility architectural/design elements will be in accordance with the New York State Department of Health regulations for medical marijuana, similar facility design standards, and industry best practices.

In addition to the regulatory requirements to which Kinex Supportive Pharmaceuticals must comply, there are valid and appropriate guidelines and industry best practices that merit consideration in the development of the security program. The guidelines developed by the various Federal Agencies are especially helpful, because they prescribe security measures for facilities with similar risk profiles. The guidelines that prove most useful for this project include:

1. U.S. Department of Justice – Drug Enforcement Administration, Controlled Substance Security Manual

2. GSA Security Reference Manual: Part 3 Design and Assessment Guidelines, U.S. General Services Administration.

3. U.S. General Services Administration - Site Security Design Guide

1.2 GENERAL ASSUMPTIONS

The general assumptions of the new Kinex Supportive cultivation and manufacturing center include:

1. The facility will sit on a four (4) acre site located in City of Lackawanna away from places of worship, public schools, playgrounds, and recreational areas. In fact, this is an area that is a recovered large industry tract, and such other locations are distant from this location.

2. Each function of the facility will have a physically separate and/or discretely secured operations and support spaces with access controlled by assignment and monitored by video surveillance and an electronic access control system.

3. The new facility will be designed to provide a minimum of 15 minutes of force protection delay on all exterior windows, walls, and doors from common “smash and grab” type scenarios.

4. The facility will be closed to the public, however visitors (contractors or third party services such as mail and package deliveries, maintenance contractors, etc.) will be allowed access onto the site only when authorized. While on site, the visitor will be escorted at all times.

5. Kinex Supportive Pharmaceuticals intends to promote an image of deliberate, consistent, and overt security for its new facility. The goals of the security program are to protect employees, the assets, and the physical site.

6. It is important that the overall environment supports the secure and closed security posture. Kinex will provide training to all employees on security policies, procedures, and reporting of suspicious activity.

7. Kinex will rely on local law enforcement for response to security issues as required.

8. For the purpose of this narrative, the cultivation and manufacturing center is considered as one joined facility.

9. IT (cyber) security is not addressed with this security program narrative.

1.3 THREATS AND VULNERABILITIES

Development of a sound security program begins with an assessment of the security threats to an organization. An examination of the Kinex Supportive Pharmaceutical's vulnerabilities with respect to those specific threats provides a valuable map to focus the security effort. The priority of the security program is to address both the most probable as well as the highest impact threats. Although a threat and risk assessment will not be completed until the construction schedule advances, similar type facilities share common risks and vulnerabilities that we can use to assist us in defining the levels of protection for this facility.

Potential threats to the cultivation and manufacturing center, its employees, and facility include:

1. Targeted physical attacks to the facility or systems. Probable methods would include small arms targeting.

2. Vandals who seek to damage the organizations assets. Probable methods would include vandalism, trespassing, electronic targeting (hacking, denial of service, etc.),

3. Theft of Kinex Supportive Pharmaceutical assets by employees, visitors, contractors, vendors, or trespassers.

4. Workplace violence, which encompasses both employee violence as well as domestic disputes that extend into the workplace.

Vulnerabilities to those threats include:

1. The facility is accessible to employees most of whom enter and depart premises in privately owned vehicles.

2. The facility is accessible to authorized visitors, most of whom are expected to arrive in privately owned or Kinex Supportive Pharmaceutical-owned vehicles.

3. The facility requires standard business services such as mail, express mail, package deliveries, food service deliveries, and waste removal services, all of which require access to the site.

1.4 SECURITY MEASURES AND CONCEPTS

A. Overall Design Approach

1. The scope of this security design effort addresses architectural, technological and operational security. The overall security program will be scalable so that it can adapt to changing threat levels and situations. Of particular importance is the ability to increase security based on credible threats and recommendations from government agencies as well as the Department of Homeland Security threat level system.

2. Given the fact that the security program will be scalable, expansion of the electronic security systems should be only limited to the capacity of the IT data infrastructure as it relates to the video surveillance system.

3. Security zones or layers will be tailored and applied to the architectural site and floor plan design to effectively create zones of separation. A key to the overall security program is the ability to build in delays, detect an incident and respond in a timely manner. This starts with the site perimeter, moves to the building perimeter and ultimately into the critical areas of the facility.

4. Security for the new facility will be designed in accordance with the NYSDOH requirements. In addition, the security program will be developed to provide a level of security consistent with similar cultivation centers and pharmaceutical facilities.

5. Kinex will employ a contracted professional armed security guard force that will be responsible for monitoring the day to day operations of the facility on a 24/7/365 basis.

6. Security personnel will liaison with local law enforcement to implement random police security checks on outer perimeter of site to help deter any criminal activity.

7. Security systems will be planned to provide effective methods of access control, Intrusion detection, visitor management, video surveillance and voice communications; in harmony with the overall architecture of the building and interfaced efficiently with other building management systems.

8. The security monitoring and control systems will be modern, state-of-the-art systems that are IP-centric and fully networked.

9. All employees will be issued a photo identification access badge color coded by responsible function within the facility. The access card incorporates smart card technology. The card along with a PIN (two form factor authentication) will allow access to the site gates, building entrance and other authorized/designated interior areas.

10. Authorized visitors and required contractors (as scheduled) will be required to identify themselves at the site entrance gate and register electronically at the guardhouse. After confirmation that the visitor is expected, the image of the visitor's face and identification will be captured and the visitor will be issued a temporary, time-sensitive visitor badge. Visitors will be escorted at all times while inside the facility.

11. A security monitoring workstation will be designed into the Main Lobby desk. This workstation will be equipped with intrusion alarm monitoring, video displays, and security control and communications equipment. The security checkpoint workstation will have the capability for event logging for all security events, investigating video, and allowing for local law enforcement to view and print while on site.

B. Site and Site Perimeter

1. Perimeter Fencing / Landscaping /Set Back

a. In order to control pedestrian foot traffic onto the site and to create a psychological/physical perimeter boundary, a fence will be provided around the perimeter close to the property line. The fence will be a minimum 8' in height and be anti-climb.

b. A Perimeter Clear Area (approximately 15 feet), on the inside of the fence will be established where possible to clear of all visual obstructions (close-cropped plants or shrubbery no higher than 2 feet above ground is acceptable).

c. The entire perimeter fence will incorporate a perimeter electronic intrusion detection system, video surveillance coverage and lighting to provide early detection alarms and assessment. The purpose of the perimeter electronic intrusion detection system is to provide early warning to security for people attempting to gain access to the site. [PHL 1004.13 (a)(1)]

d. Landscape elements will function as passive security barriers to maintain vehicle set back distances for the facility. This may include berms, drainage trenches or retention ponds.

2. Vehicular Traffic

a. A single point of entry will be utilized for vehicular access to the site. All vehicular traffic will be controlled using motorized sliding anti-climb fence-type gates that will serve as a portal through which employees and visitors can access the on- site surface parking area. Employees will only be granted access to the secure parking areas after electronic (card reader) or operational methods verify their authorization to enter.

b. A guardhouse will be placed at the vehicle entry to the site to monitor vehicular entrance and exit traffic and control access to the site. The guardhouse will be staffed by armed security officers, during the first and second shifts. The guardhouse will have direct communications to the security office at the main lobby as well as video surveillance monitoring capabilities, and access control technology. This post will control vehicle entries, validate visitors and provide excellent visual surveillance of the surface parking lot and site grounds.

c. Video surveillance cameras will be provided at the vehicle entry and exit points for general surveillance, vehicle identification and identifying the vehicle driver. In addition, specialized cameras will be utilized to capture inbound and outbound license plate information for record keeping purposes.

d. Access control card readers and IP based intercom will be provided at both the inbound and outbound traffic lanes.

e. The gap at the bottom of the gate will be small enough (no more than 6”) so that an individual cannot crawl underneath the gate.

f. The gates will have the capability to be controlled locally via access badge and through the access control software at the main lobby security desk.

3. Parking Security

a. Parking on-site beyond the secure checkpoint will be restricted to employees and screened visitors.

b. To separate the on-site parking from the facility landscape features (berms, swales, etc.) will be utilized.

c. The parking area will be equipped with adequate security lighting to the

maintained illumination levels recommended by IES Lighting Standards.

d. The parking area will be equipped with strategically located IP video cameras to provide surveillance of parking access points and the general lot.

4. Lighting

Lighting is an essential security element in order to deter crime, to detect, recognize and identify individuals and scenes and to convey a safe and orderly environment. All exterior areas of the site, site entrance and exit, perimeter fence, and general ground will be equipped with adequate security lighting to the maintained illumination levels recommended by IES Lighting Standards or to local standards.

a. General - A minimum level of reflected 0.5 foot-candles of light is necessary for detection, 1.0 foot-candle is necessary for recognition and 2.0 foot-candles are necessary for identification. Roadways and pedestrian approaches are lighted for safety and security reasons, so their light levels will be higher than the minimum standard. Because site video surveillance will be use used, luminary and fixture designs that reduce glare at the video camera lenses will be utilized.

b. Site - At the perimeter, a minimum level of 0.2 foot-candles of reflected lighting will be utilized.

c. Surface Parking - At open parking, a minimum level of 0.5 foot-candles of reflected lighting will be utilized.

d. Building entrances and facade - a minimum level of 2 foot-candles of reflected lighting will be utilized.

e. Loading docks - At exterior loading docks the minimum level of reflected lighting will be 1 foot-candle by doorways, 0.2 foot-candles in open spaces, and 5.0 foot-candles at night time if and when receiving and shipping is active. At interior dock areas and bays, the minimum level of reflected lighting will be 15 foot-candles, 20 foot-candles for unpacking and sorting areas and 30 foot-candles for packing and dispatching areas. [PHL 1004.13 (e)]

5. Utility Protection

a. Building utility services will be located in such a way as to prevent intentional misuse, damage and removal of the services by unauthorized persons. Vital equipment will be located to minimize damage or destruction from an attack. Any equipment on the exterior of the building near vehicular traffic will be protected by anti-ram security bollards.

b. Locking covers will be provided for all manhole covers, handholds, drainage grates, etc. located within the site.

c. Forced entry grilles will be provided inside storm sewers that cross the perimeter fence line when the sewers are larger than 96 sq. in.

C. Building Perimeter:

1. Employees and visitors will enter the facility from a single location via the on-grade surface parking lot. Standard Deliveries (UPS, FedEx, etc.) will enter through the main lobby and not the loading dock. The loading dock will only to be used for the transportation of materials and supplies utilized by the facility.

2. Controlled access to the facility will be employed at all times (24/7).

3. All exterior emergency exit doors will be locked from the inside with no exterior hardware. These doors will be monitored and provided with video surveillance covered.

4. All exterior doors to the facility will be provided with video surveillance to record and monitor the associated activity.

5. All perimeter doors that provide direct access to the production area of the facility will be equipped with security hardware that provides 15 minute forced entry rating protection. Doors will be out-swinging (away from the protected spaces). All security doors with exposed hinges will have the hinges pinned in such a way as to prevent their removal. The construction of these doors will be commensurate with the surrounding wall construction.

6. All exterior, non-window wall penetrations that exceed 96 square inches in total area, with its smallest dimension greater than or equal to 6 inches, will contain man bars to prevent surreptitious entry. The man bars will be at least ½" affixed on 6" centers both horizontally and vertically. The junction point of the man bars will be welded to prevent spreading.

7. Building air intakes and all vent openings greater than 96 square inches will be elevated at least 15 feet above grade or as high as practical. The openings will be protected with security screens across the intakes and they will be located within video surveillance camera views so that the cameras will capture any activity near the intakes.

8. All perimeter windows including windows within doors will be equipped with a minimum 8 layer security window film to delay and deter "smash and grab" type attacks. Glass break sensors will provide a secondary means of monitoring the perimeter windows by alarming on the acoustical sound of glass

breakage.

D. Building:

1. Main Lobby

a. All employees and visitors will utilize the main lobby as a singular entry point into the building. All other perimeter doors with the exception of the loading dock will be configured as egress only. The main entrance will be a secured two-door vestibule that will require employees to badge in in order to gain access to the security lobby. Visitors will be required to utilize an IP based video intercom at the vestibule door in order to be granted access into the secure lobby.

b. Controlling and maintaining a positive level of security in the main lobby is critical to the overall security plan as this is the main separation point between employees and visitors to the facility. Security officers will be staffed at this location to provide a positive level of security.

c. All visitors entering the facility will check in at the lobby security desk and then wait for an escort. Visitors will only be allowed beyond the security lobby escorted by an authorized employee.

2. Main Lobby Security Desk

a. The facility will be equipped with a security post that provides monitoring on a continuous 24/7 basis. Local monitoring is a critical component of the security program and will be designed to provide both redundancy and survivability. The main purpose of the post is to provide a central location for security to monitor all access control, intrusion detection, video surveillance cameras, and communications in addition to providing security officer response in the event of an emergency. Building systems such as, fire monitoring, and utilities will be passively monitored by security at this location.

b. The security monitoring post will provide enough space for one operator and the associated monitoring equipment along with direct visual observation (windows) of the entry lobby and main walk-up pathway.

c. The security post will be equipped with a duress, panic and hold-up alarm. The alarms will be monitored by a third party UL listed central command center which will validate and dispatch local law enforcement to the facility, in case of an emergency and/or life threatening situation.

d. The security post will be equipped with an automatic voice dialer, which

will be capable of sending a prerecorded voice message to local law enforcement in case of an emergency and/or life threatening situation.

e. The security equipment in the main lobby will be provided with UPS power to provide line conditioned and continuous power in the event of a power loss. A backup generator will be utilized in power outage situation with a minimum of 160 hours of run time. At a minimum, 160 minutes of UPS power will be provided.

f. A backup, state of the art, alarm system will be in place, which will be separate from the primary security system, for detection of any unauthorized access to the facility during non-working hours.

3. Loading Dock

a. The loading dock area will be equipped with access control, IP intercoms and video surveillance coverage. The overhead doors should be locked and only opened from the inside by security after verification that the delivery is authorized.

b. In order to ensure positive control into the facility from the loading dock, an interlock door configuration will be implemented. An interlock configuration is where two sets of doors are installed but only one door could be open at a time. When deliveries are made, the overhead door is left open and the interior door tends to be propped open potentially allowing direct access into the sensitive areas of the facility. Implementing an interlock door configuration will eliminate the possibility of propping doors open.

4. Office Space

a. The office function area will be physically separated from the production side of the facility.

b. Windows in the office space area shall be protected with glass break detectors and motion detectors. In the event a glass detector fails to detect the acoustical sound of breaking glass (most likely do the force protection film) the motion detector acts as a secondary means of detection.

c. Video surveillance cameras will be located to cover the general reception area and entry points into and out of the office suite.

d. Access control card readers shall be placed on the office entry door to record access into and out of the space.

5. Production space within cultivation and manufacturing center.

a. The production area will be physical separated from the office function area

of the facility.

b. The main entry into production space will be card reader controlled on both sides of the door to log inbound and outbound traffic. PIN entry will be required to enter the production space while existing will only require a valid card swipe.

c. Each function space within the production area will be compartmentalized and card reader controlled off of a common corridor.

d. Non-production use rooms such as Storage and Mechanical shall be card reader controlled to monitor entrance and exit activity.

e. Video surveillance cameras shall cover all areas of the production space. Two types of cameras will be utilized, HD digital fixed cameras for surveillance of critical areas and HD 360 degree cameras for general surveillance. The purpose of the 360 degree camera is to capture general activity and situational awareness within designated areas of the production facility.

f. All perimeter doors and windows will be monitor by intrusion detection devices. Windows will be monitored by glass break sensors and perimeter rooms will be monitored by motion detectors. Perimeter doors will be monitored by door contacts, including the roll-up doors in the loading area.

g. A designated vault, approved by the NYSDOH, will be placed to secure product. The vault will be a stand- alone third party provided and installed. The vault area shall be monitored by video surveillance and motion detectors. The vault will only be accessed by authorized personnel and each entry will be recorded.

6. Cultivation areas

a. The cultivation area shall be equipped with access control on the main entry portal. Card readers shall be equipped on both sides of the door to monitor and record ingress and egress into the facility.

b. All areas within the cultivation areas shall be covered with general video surveillance. Due to the arrangement and equipment required within the green house, main pathways will be covered as well as the entry and exit portals. 360 degree cameras will be utilized to provide general surveillance of the area while fixed, high definition cameras will be used to produce identifiable images at the entry points.

c. Emergency egress doors within the cultivation area will be equipped with door monitoring contacts, local sounders, and video surveillance coverage. Signage will be posted to warn employees not to open the doors unless it is an emergency.

d. Motion detectors will be positioned to monitor the space above the cultivation area. This will provide protection from an intruder attempting entry from the roof of the cultivation area while mitigating false alarms due to movement of plants.

2.1 SECURITY SYSTEMS DESCRIPTION

A. The technical security systems provided will be scalable and capable of being expanded to handle the on-going evolution of the facility and security requirements as well as building modifications at a later date. The technical security systems installed at this facility will be designed as enterprise systems.

B. The security monitoring and control systems will be modern, state-of-the-art systems that are IP-centric and fully networked.

C. Within the building, conduit will be used for all security systems cabling. All security system cabling will be low voltage cabling only. Conduit is being provided to accomplish an enhanced degree of protection for the security equipment.

D. The security system will utilize the common IT backbone infrastructure for all the security system communications. Security will be a VLAN setup allowing for privacy and secure image transmission with the facility, however it will utilize the same common networking infrastructure.

E. The security systems throughout the building will be provided with uninterruptible power for a minimum of 160 minutes of run-time.

F. The security system will have a failure notification system in place, which will send a notification to the manufacturing facility or dispensing facility with five (5) minutes of the failure.

G. Lockable vertical equipment racks will be used for housing all equipment for the security systems. The wall mounted security equipment including field panels, power supplies, transformers, converters, will be located in IT closet which are card reader controlled. Video surveillance storage servers will be located in the lockable rack enclosure. Surveillance equipment will be accessed by authorized personnel only. A list of authorized personnel having access to surveillance equipment will be maintained.

H. Any lock combinations, passwords, entry codes will be secured properly and will not be accessible to any unauthorized personnel.

I. The access control and alarm monitoring system and the digital video system will be provided with a single platform interface. Hardware and head-end equipment for these systems will be separate, however, the single platform interface will provide for seamless integration.

J. A visitor management system will be provided that includes software, workstation, and a badge printer that is interfaced directly into the access control and alarm monitoring system. The purpose of the visitor management system is to document and record a log of all visitors to the site. The visitor management system will be configured such that confirmed visitors will be issued paper badge displaying the visitor name; employee visited, and date of visit. At the end of each visit, the visitor will return the badge to security.

K. The access control and alarm monitoring system, digital video system, and visitor management system will interface and/or communicate on the IT network. All security related communications on the network will be on a segmented portion of the network (Security VPN).

L. Security personnel will have a digital radio communication system, with a unique channel, that is used throughout the new facility for coordinating security and business operation needs.

M. All "actions or clicks / manipulation" conducted within security software (access control and video) will be recorded for auditing purposes.

2.2 ACCESS CONTROL AND ALARM MONITORING (ACMS)

A. An access control and alarm monitoring system (ACMS) will be provided to monitor and control all access control and alarm monitoring devices. The ACMS software shall be of enterprise quality and be capable of interfacing with the video surveillance system and intrusion detection system. The ACMS acts as the central monitoring point of all security systems so that the security operator only utilized one interface for assessing alarms and performing administrative tasks.

B. The ACMS software shall run on a dedicated server that is RAID 5 configured with dual power supplies. RAID 5 configuration will ensure that if a hard drive fails, critical data is not lost or corrupted and the system will still function.

C. The ACMS will communicate via the network. Connections to the network will be provided at ACMS server, field panels, and operator workstation. The ACMS will communicate over the network on a dedicated segment of the network.

D. Software will be the manufacturer's standard software package with use of extra options such as advanced alarm graphics or GUI interface capable of importing CAD drawings, video surveillance interface and visitor management software.

E. A visitor management system will be provided as an integrated component of the ACMS. The visitor management system will allow security to enroll and pre-authorize visitors into the system.

F. The ACMS will incorporate a perimeter electronic intrusion detection system around

the entire perimeter fence to provide early detection alarms and assessment. The perimeter intrusion detection system will be interfaced with the video surveillance system to provide visual assessment upon an alarm condition.

G. ACMS workstations will be provided at the security lobby desk which will be capable of displaying the digital photo images.

H. All perimeter doors of the building will be provided with alarm monitoring through the use of door position switches. Perimeter emergency exit doors will also be equipped with local audible alarms.

I. Access control through the use of card readers or card readers with PIN will be provided within the facility. A typical access controlled door configuration would include: card reader, door position switch, request-to-exit device, and electrified locking hardware. A typical access controlled door configuration for areas requiring audit capabilities would include: card reader with PIN for entry, card reader with Pin for exit, door position switch and electrified locking hardware.

J. Vehicle access in and out of the site will be controlled via electronic identification (badges) and the use of sliding gates. The ACMS will be interfaced to open the gate sliding gate when necessary upon access being granted.

K. Duress buttons will be provided and integrated with the ACMS and a third party Central Monitoring Station to signal emergency situations. Below are the main areas that will be provided with coverage.

1. Main lobby security office
2. Loading Area
3. Vault Area
4. Office Receptionist
5. Green House

L. The ACMS equipment will be interfaced to the video surveillance system for automatic call up and recording of video surveillance system cameras.

M. The ACMS will be interfaced to the fire alarm system where required by code for unlocking of various access controlled doors in fire alarm situations.

N. Security patrols will utilize an integrated Guard Tour system that is built into the ACMS for verification of security officer patrols and time keeping. The purpose of the guard tour system is to keep the security officer honest while on patrol. The guard tour system requires the security officer to physically swipe a badge on a card reader in designated locations during patrol. If the officer fails to patrol all areas, a report will be generated showing the missed patrol.

2.3 VIDEO SURVEILLANCE SYSTEM

A. The Video Surveillance System (VSS) will be a dedicated, IP-Based system utilizing the LCG business network.

B. The VSS system will be composed of IP-based video cameras, client workstations, and network video recorders.

C. The VSS system shall utilize Category 6 cabling for the video cameras. Fiber optic cabling will be used at all exterior cameras or for cameras over 300' from the Power of Ethernet network switches.

D. Video images will be displayed over the IP network at the main lobby security desk and within the mangers office. Video images will have a date and time stamp embedded on all recordings and will have the ability to produce still images that are a minimum of 9600 DPI.

E. The IP based VSS will be used to record the camera signals on dedicated RAID 5 hard drives, which can store a minimum of 90 days of recorded images before trickling (sending) recorded information to an off-site cloud based storage area for an additional 90 days. The VSS software will be able to analyze / investigate video no matter the physical location of the video.

F. System tests will be conducted on a bi-weekly basis to ensure that all surveillance equipment is in proper working order. All tests will be recorded and records will be maintained for a minimum of five (5) years.

G. A combination of fixed and moveable surveillance cameras will be provided to monitor interior and exterior spaces of the facility.

    1. High definition digital fixed surveillance cameras will be utilized for direct coverage of critical areas and be capable of capturing images in low light.

    2. High definition moveable (PTZ) surveillance cameras will be utilized on the exterior of the facility for situational awareness and patrol of the perimeter fence.

    3. High definition digital 360 degree cameras will be capable of displaying a full 360 degree image will be utilized for general surveillance in the production area. The purpose of this camera is to provide an overview of activity while the fixed cameras provide high quality identification images.

H. The VSS system will be interfaced to the ACMS for automatic call up and recording of video surveillance system cameras.

I. Moveable cameras shall be provided with alarm prepositioning capability, which allows automatic call up of preprogrammed scenes. Designated cameras shall also utilize basic video analytics that are included with the video management system

software.

J. Fixed VSS camera locations shall be designed for PoE and will be powered by the associated network switch. Separate power supplies should not be required.

K. Exterior moveable camera locations shall be designed for high PoE and utilize a local power injector, which are located in the vicinity of the camera location. A local 120 VAC circuit shall be utilized for electrical power.

2.4 INTERCOM COMMUNICATION SYSTEM

A. An IP based intercom communication system will be provided for communications between security posts/officers and for direct communication with security from intercom substations or assistance call stations.

B. Intercom stations will provide two-way hands free communication from the station location to the main security lobby desk. Intercom stations will be used at the following locations:

1. Main entry perimeter door
2. Vehicle entrance and exit point to the site
3. Entrance/Exit to the cultivation and manufacturing center.
4. Loading Dock Area
5. Vault Area

C. The intercom communications system will be interfaced to the VSS system for automatic call up of VSS cameras when an intercom substation is activated.

3.1 SECURITY STAFFING OVERVIEW

The physical layout of the new facility, the nature of work performed there and the size and flow of people into and out of the facility ultimately determines the number and types of security posts that will be required to protect the site, facility and its occupants. The number of security officers and supervisors continues to be refined, in part through planning for early and subsequent patient activity patient volume will be an important factor determining security staff levels and by type to code those posts and provide basic levels of protective functions including controlling and monitoring the movement of pedestrians at entrances, vehicles in parking areas, and people into the facility. The security force will ultimately be responsible for providing a secure work environment, observing life safety functions and responses, responding to emergency and disturbance situations,

providing selective escorts of valuables and personnel, providing building control functions, and performing special assignments as directed.

The security program utilizes the security monitoring desk at the main lobby to monitor designated alarms and alerts, assess situations and respond to security breaches within the building interior or outside around the perimeter and exterior site, as well as, to monitor access control operations, be first responders to fire and safety events, and to initiate and relay critical communications. The combination of security officers at fixed posts with mobile security officers on roving patrols or responding to security incidents will provide the proper level of protection and control for the new facility.

The following security principals are essential to building the appropriate size and type security force:

A. Controlling and Monitoring

Security posts are defined depending on the geometrics, people, materials and vehicular movements, and the in-and-outs of both building and grounds. These posts control the movements to effectively allow for orderly and authorized movements and deter or deny any unauthorized entry or exit.

When the security force is assigned to a specific location it is labeled a fixed post. Typical fixed post assignment includes reception areas, loading docks, and entrances to the site.

When the security force is assigned to move throughout the building and grounds it is labeled roving patrol. Typical roving patrol assignment includes traveling by foot, bicycle or vehicle at predetermined and alternating stations covering the building interior, building exterior, parking lots, and site or as conditions and situations are warranted. This position must remain flexible to adapt and respond to security breaches and issues.

Observation and reporting are the objectives under both of these functions to facilitate services and rapid responses in a timely manner.

B. Assessing and Monitoring

The Main lobby security desk serves as the local center of operations for communications and managing responses. A major role is the monitoring of alarms and alerts for intrusion detection, duress and to dispatch security rapid response as situation or conditions warrants.

Observation, dispatching and reporting are critical objectives under this function to assure the deployment of security, law enforcement fire and life safety, and service/maintenance in a responsive and timely manner.

C. Conducting Inspections

The security guard force is responsible for conducting regular and irregular patrols to assess the building, grounds and life safety, to respond to emergency or service calls, and to deter undesirable behaviors by assuring the required adhering to the strict organizational policies and procedures.

Observation and reporting are objectives under this function to alert the local security office and request assistance, service or critical maintenance responses in a timely manner.

D. Selective Escorts and Assignments

The security force may be asked on few and selected occasions to escort individuals to and from vehicles and when in possession of valuables.

3.2 SECURITY OPERATIONS

The protection strategy, as previously mentioned, will be based on a comprehensive and balanced plan integrating architectural features forming layers of protection directed inward, followed by the integration of security technology to leverage security force efforts and to compliment the protective layer approach and by the deployment of a security work force organization to implement the protection strategy.

Despite the deployment of effective architectural and technological security measures and systems, the security program will also include an operational security officer organization to observe operations and ensure that the security measures and systems are being monitored properly and there is quick response to breaches. The security officer work force will be employees of Kinex Supportive Pharmaceuticals, LLC, and directed by the organization's Director of Security.

A. Nature and Scope

The nature of the work is that of a full security officer/guard work force to provide protective services. The scope of the security work force includes basic protective functions like controlling and monitoring the movement of pedestrians and vehicles by entrances and exits, assessing and monitoring the building interior, perimeter and exterior, monitoring alarms and alerts for access control, fire safety, and communications, conducting inspections of security and life safety, responding to emergency and disturbance situations, providing selective escort of valuables and personnel and special assignments as required.

B. Number and Types of Officer Posts

A total of three (3) posts will be utilized at the facility.

1. One (1) fixed post will be assigned at the Lobby security desk. This

position will be configured to monitor designated security and facility systems and dispatch security or fire/police responders when requested or required. This position will also verify employees and visitors accessing the main lobby and entering the facility providing for a positive access control mechanism.

2. One (1) fixed post will be assigned at the site entrance guardhouse. This post will provide visitor check in and employee verification, confirm and screen delivery vehicles, provide visual surveillance to the main and parking areas, and deliver a message that security is present on the site. It is anticipated this post will only be staffed for two (2) shifts during daily operations.

3. One (1) roving patrol post will be assigned assuming building, parking lot and site deployment. The roving patrol will respond to various alarm activity, provide random patrolling tours of all facilities and grounds, perform scheduled checks on life safety and facility applications and conduct special assignments as directed.

C. Transportation of Product

The transport of any approved medical marijuana product will be made in a NYSDOH approved vehicle and will be staffed with a minimum of two (2) armed security personnel. At least one (1) security personnel will remain with the vehicle at all times during the transport.

During the transport of approved medical marijuana product, authorized personnel will have a radio communication system, utilizing a unique channel which communicates between the vehicle and the manufacturing site. Security personnel will also have cellular phones with GPS technology as a backup to the radio communication system. The vehicle will also have a GPS satellite locator.

The transport of any approved medical marijuana with be randomized. The transport times and days will vary, to help reduce predictability.

The transport vehicle fleet will consist of a minimum of three (3) vehicles, of different makes and models, to reduce predictability during transport of product.

The approved medical marijuana product will be secured in a locked safe/storage compartment. The safe itself will be fashioned so it is permanently secured to the vehicle and the safe will not be visible from outside the vehicle.

An approved shipping manifest, approved by the NYSDOH, will be completed prior to each transport of approved medical marijuana product. These manifests will be retained for a minimum of five (5) years and will be made available for inspection upon request by the NYSDOH.

A copy of the manifest will be transmitted to the dispensing facilities at least two (2) days prior to the shipment of product. Authorized personnel transporting the product will

possess a copy of the manifest with them at all times and will produce the manifest when requested by law enforcement or any other authorized representative of the local, state, or federal government.

Approved medical marijuana product will only be transported from the manufacturing facility to the dispensing facilities, with no unnecessary stops.

Redacted pursuant to N.Y. Public Officers Law, Art. 6

SHANE T. HUTTO

[redacted]

PROFILE

Disciplined and energetic plant lover with Horticulture degrees, advanced interpersonal skills, and diverse greenhouse success, and track record of innovating by applying critical thinking, knowledge, and design principles with consistent results, and improving processes with creativity and natural leadership abilities.

- **Core Proficiency Areas:** Consulting, Operations Planning, Facility Design, Optimization, **GAP**, Research Trials, Statistical Analysis, Manuscript Development, Pesticides, Processing, Post Harvest, Extraction, Value added products, Packaging and Storage.
- **Crop Highlights:** Cannabis, Cilantro, basil, spinach, pecans, peppers, poinsettias, mums, bedding plants, annuals, perennials, herbs, vegetables, mushrooms, annatto, paprika, and jojoba, and more.
- **Software:** Microsoft Office (Word, PowerPoint, Access), AutoCAD, FrontPage, SAS, and Advanced Excel user.

EDUCATION

M.S. in Horticulture, Cilantro production and extraction using liquid propane, completed courses 2011
Oklahoma State University, Stillwater, OK

- **Course Highlights**: Lab experimentation, statistics, SAS, temperature stress, water relations, postharvest, flowering and fruiting, plant pathology, physiology, plant materials, propagation, entomology, plant biology, soil nutrients, commercial vegetables, and greenhouse management.

B.S. in Horticulture, Focus in Greenhouses, Soil Science minor, 2008
Oklahoma State University, Stillwater, OK

- Achieved President's Honor Role two semesters.
- Tutored student in four science classes and mentored and coached on graduate school decisions.

PROFESSIONAL EXPERIENCE

[redacted]

Oklahoma State University Hazardous Reactions Lab – Stillwater, OK May 2008 – May 2011

Research Assistant, Continuous flow propane extraction

Ran extraction lab and performed extensive field research, ramping up quickly from a lab assistant, earning trust to use high profile, dangerous equipment, independently operating the lab and conducting experiments from sample weighing to processing to packaging. Cleaned high-tech systems and lab.

- **Research –** Designed cilantro growing field trials with different treatments. Oversaw and harvested up to 100, 1/10 acre plots per season. Processed and dried cilantro samples and recorded variances. Packaged, stored, processed, ground, and separated samples, and ran through extraction machine.
- **Analysis** – Performed color analysis, chemical profile analysis, fat content, moisture content, and bulk density.
- **Specialized equipment** – Operate rare, specialized propane extraction unit using liquid propane, colorimeter, and gas chromatograph with flame ionization detector (GC-FID). Handle chemicals using fume hood and analytical balance to achieve a degree of extraction.
- **Process Improvements** – Reduced lab cleaning from a six hour process to a three hour process. Streamlined cilantro washing, reducing time from two days to a six hour process.

Professional Experience, Continued…

Oklahoma State University – Stillwater, OK Apr. 2006 – May 2008

Assistant Lab Coordinator, Controlled Environment Research Laboratory

Multi-tasked as proactive, dependable leader, progressing from entry level role to independently managing greenhouse operations, growth chambers, and lab operations reporting to lab coordinator. Leveraged success to negotiate unheard of raise.

- **Engineering** – Designed and performed plumbing and carpentry to build a high profile catfish farm still in use for Zoology Department with no budget, including a cooling and air system over six months. Supervised an assistant to build structure meeting university physical plant standards.
- **Project Management** – Planned and built a vapor barrier in an existing building, troubleshooting and wiring electricity for challenging project with multiple attached, overlapping runs.
- **Leadership** – Trained an employee on greenhouse and growth chamber maintenance.
- **Greenhouse Maintenance** – Installed new greenhouse components including polycarbonate and plumbing.
- **Greenhouse Equipment** – Mastered, operated, troubleshot, and repaired fans, vent louvers, watering equipment, fertilizing injectors, heaters, and cool tubes.
- **Maintained Growth Chamber** – Repaired fans, bulbs, thermostats, and computerized controls.

65 Franklin Street, Room 601
Buffalo, New York 14202

June 1, 2015
Kinex Supportive Pharmaceuticals,

In order to comply with the Compassionate Care Act application, proof of internet access from a local service provider is needed. More specifically, attachment K calls for proof that all applicants' manufacturing and dispensing facilities are located in an area with internet connectivity. For the dispensary location at Electrical Stores Building, Tecumseh Site, 2303 Hamburg Turnpike, Rte 5, Lackawanna, NY 14218. Verizon has services HSI & Hicap services available in the area [HSI is High Speed Internet (DSL) - up to 3Mb, hicap services – DS1, DS3, Ethernet].

Sincerely,

Carolyn Yunke

Carolyn Yunke
OSP Network Engineer – Design
65 Franklin St, Flr 6
Buffalo, NY 14202

O: (716) 840-8621
[redacted]

Attachment J. Staffing Plan

Position Title	Experience/ Qualifications	Position Description	Persons FTE	Reports	Status: Hired/To Be Hired
Chief Executive Officer	10-15 years experience in pharmaceutical manufacturing	-Oversees company management; responsible for establishing company's strategic goals and direction -Implementation and continued development of best practices -Development of a program to enable patients with limited resources to obtain medical marijuana at no or little cost	1 FTE	BOD	Hired
Chief Financial Officer	Provided by Kinex Support agreement.	Responsible for all Financial Management and operations for Kinex Supportive Pharmaceuticals LLC	1 FTE	CEO	Hired
Chief Operating Officer	10-15 years' experience with development and operations in the bio-pharmaceutical industry. Knowledge about	-Oversight of cultivation, manufacturing and distribution operations. -Responsible for	1 FTE	CEO	Hired

	operations and service distribution in the medical marijuana field preferred.	dispensary level services to registered patients. - Directs improvement strategies that relate to operation performance and improvement with product. Cooperates with Director of Clinical Pharmacology and Regulatory Affairs on reporting to NYS, and also requests to NYS on matters and changes affecting patient service and experience with medical marijuana services. Responsible for implementation strategies for Kinex medical marijuana program.			
Director of Quality Assurance	5-10 years experience in Quality Assurance and validation	-Leads all quality assurance activities across organization.	1 FTE	COO	Hired

		-Trains and leads staff with QMS policies and procedures. -Conducts audits and root cause analysis on subjects requiring investigation. -Supports management reviews with metric development and measurement intervals. -Performs gap analysis as part of quality management systems. -Develops new quality capabilities within organization.			
Director of Clinical Pharmacology & Regulatory Affairs	5-10 years experience with Pharmacological data analysis supporting drug development, quality assurance	-Formulates and conducts data based studies to insure cultivation and manufacturing standards are being met.	1 FTE	CEO	Hired

	and insuring requirements with production and regulatory standards. -Experience with investigation and resolution of deviations and variances with production. -Experience in pharmaceutical, medical device and biotech production environment.	-Assists with regulatory reporting as required.			
Director of Laboratory and Device Production	5-10 years experience in fields of chemistry, bio-chemistry, molecular biology, infectious disease, structural biology and drug design and discovery. -Experience with laboratory management, business development, GMP manufacturing preferred.	-Oversees quality through management of laboratory. -Supervises testing of products and intermediates. -Supervises testing of cultivation and manufacturing environment. -Conducts tests, reviews, and qualifies condition	1 FTE	COO	Hired

		of analytic equipment.			
Director of Agriculture and Cultivation/Head Grower	5-10 years' experience in commercial cultivation experience with knowledge of botany, nutrient profiles, irrigation techniques, pesticides, fungicides, and production standards -Experience with many crops, with 3-5 years of cannabis specific growing on commercial scale.	-Manages Growers; Trimmers -On Site at the Cultivation Manufacturing Facility each day, except for scheduled vacation or sick time -Manages issues pertaining to crop failure, disease and mechanical failure in the Cultivation Center -Documents soil/nutrient mix for each type of plant grown and oversees the mixing of such soil/nutrients -Monitors/ manages temperature and humidity for rooting, vegetative, and flower stage and for drying	1 FTE	COO	To Be Hired

		-Tags all plants in accordance with inventory policy and procedure -Manages/ monitors all lighting necessary for rooting, vegetative and flowering stages -Trains all Growers, Trimmers, and MIP Processors -Oversees daily operations and staff to ensure compliance with the Department of Agriculture			
Assistant Cultivation General Manager	-Background in commercial production. Must be mechanically inclined with experience in staff management. Commercial Pesticide Applicators License for Vegetable Crop pest control	-Supervise cultivation staff including establishing work schedules, assigning tasks and responsibilities, performance evaluations -Tags all plants in accordance with inventory policy	1 FTE	Director of Agriculture and Cultivation	To Be Hired

		and procedure -Maintain cultivation files and records. Training for research and staff on Worker Protection Standards, Forklift procedures, Pesticide Applications, etc. -Ensuring cultivation of cannabis is contaminant free -Refine IPM (Integrated Pest Management) as it pertains to cannabis			
Gardeners	Experienced in botany, commercial gardening or agriculture.	-Takes cuttings from mother plants and roots the cuttings before planting.	11 FTE	Assistant Cultivation General Manager	To Be Hired
Trimmers	No experience necessary (on the job training) Fine motor skills comfort level. Demonstrated excellent work	-Machine and hand trims flowers -Place trimmed flowers and trim into jars for curing	5 FTE	Director of Agriculture and Cultivation	To Be Hired

	ethic.				
Inventory Control Manager	Minimum of five years IT experience in inventory management involving tracking software and logistics. Experience in high risk production or manufacturing facility preferred. A four year degree in computer and/or supply chain management preferred. Demonstrated excellent work ethic in prior positions	-Oversees all storing, tracking, counting, and safekeeping of cash, medical marijuana and other ancillary products (for consumption of cannabis) -Print labels for the final product medical marijuana and affixes the same to appropriate containers -Performs the daily/ weekly/ monthly inventory audits for the Company. -Counts all receipts in the Cash Vault at the end of each business day -Weighs all product with Trimmers	1 FTE	COO	To Be Hired
Director of Security	15 -20 years on a police force	-Recruit, Assign, Direct and Supervise all	1 FTE	COO	Hired

	-Knowledge of NYS laws, legal codes, government regulations and agency rules. -Experienced in unit leadership and possess excellent communication and interpersonal skills. -Experience with staff training. -Experience with investigations, risk/theft assessments, quality control related to security operations preferred.	security officers. -Train security officers including familiarity with NYS regulations, scope of role and duties described in security plan and related documents. -Insure all certifications with security officers as needed, are current and up to date. This includes firearm proficiency, auto drivers licensing, and first responder on higher training. -Participate and advise management, architects, and construction team on security considerations with construction of manufacturing centers and dispensaries, including all alarm and communication			

		systems. -Communicate and advise, on a regular basis, local law enforcement agencies with regard to operation and activities at manufacturing center and dispensaries. -Participate with other members of management team with management reviews of operations and other quality management studies.			
Security Officer-Couriers	Former police officer, auxiliary police officer, police officer on detail, veterans licensed as armed security guards Valid driver's license	-Delivers medical cannabis to dispensaries	4 FTE	Director of Security	To Be Hired
Security Officer	Former police officer, auxiliary police officer, police	-Maintains the safety and security of Cultivation	6 FTE* May overlap with Couriers	Director of Security	To Be Hired

	officer on detail, veterans licensed as armed security guards Valid driver's license	Center employees -Maintains safety and security of dispensary staff to ensure the safety of cannabis plants and the final cannabis products			
Dispensary Staff					
Dispensary Pharmacist	Must possess an active NYS pharmacist license. Must complete NYSDOH education course on medical marijuana. 1-2 years experience in retail pharmacy. Experience with directly providing to patients information about use of lesser known products with attention to their use and potential risks. Experience with pharmacy security and distribution control procedures. Prior experience with staff supervision. Insures dispensing	-Organizes dispensary operations consistent with Kinex Supportive policy and procedure. - Supervisor of all dispensary functions. - Supervises dispensary staff with their assigned duties. - Cooperates with security/courier staff as well as other Kinex Supportive personnel. - Adheres to infection control and other environmental procedures and	1 FTE per Dispensary	COO	To Be Hired

	regulations, policy, procedures, and reporting requirements are followed, and likewise for product disposal. Prior experience with a secure service environment preferred.	rules. - Provides product information to certified patients or certified caregivers as alternative reuse of product, possible effects, and risks.			
Pharmacy Technician	One year of experience in a retail environment with active contact with customers. Experience in a retail pharmacy preferred. High School diploma or comparable required.	Under supervision of licensed pharmacist, provide medical marijuana products to certified patients or certified caregivers according to established procedures and training. Duties include: - Perform routine tasks under supervision of pharmacist to help prepare product for receipt by patient. - Perform administrative duties such a telephone or	1 FTE per Dispensary	Dispensary Pharmacist	To Be Hired

		email communication, monitoring and stocking products, validation of patient information at time of appointment, assist pharmacist as directed during patient encounters. - Receive payment and complete purchase transaction with patient.			

Redacted pursuant to N.Y. Public Officers Law, Art.6

Education

Ph.D. 2001, Synthetic Organic Chemistry, State University of New York at Buffalo, Buffalo, New York.

B.S. 1995, Chemistry, Canisius College, Buffalo, New York.

Other Skills

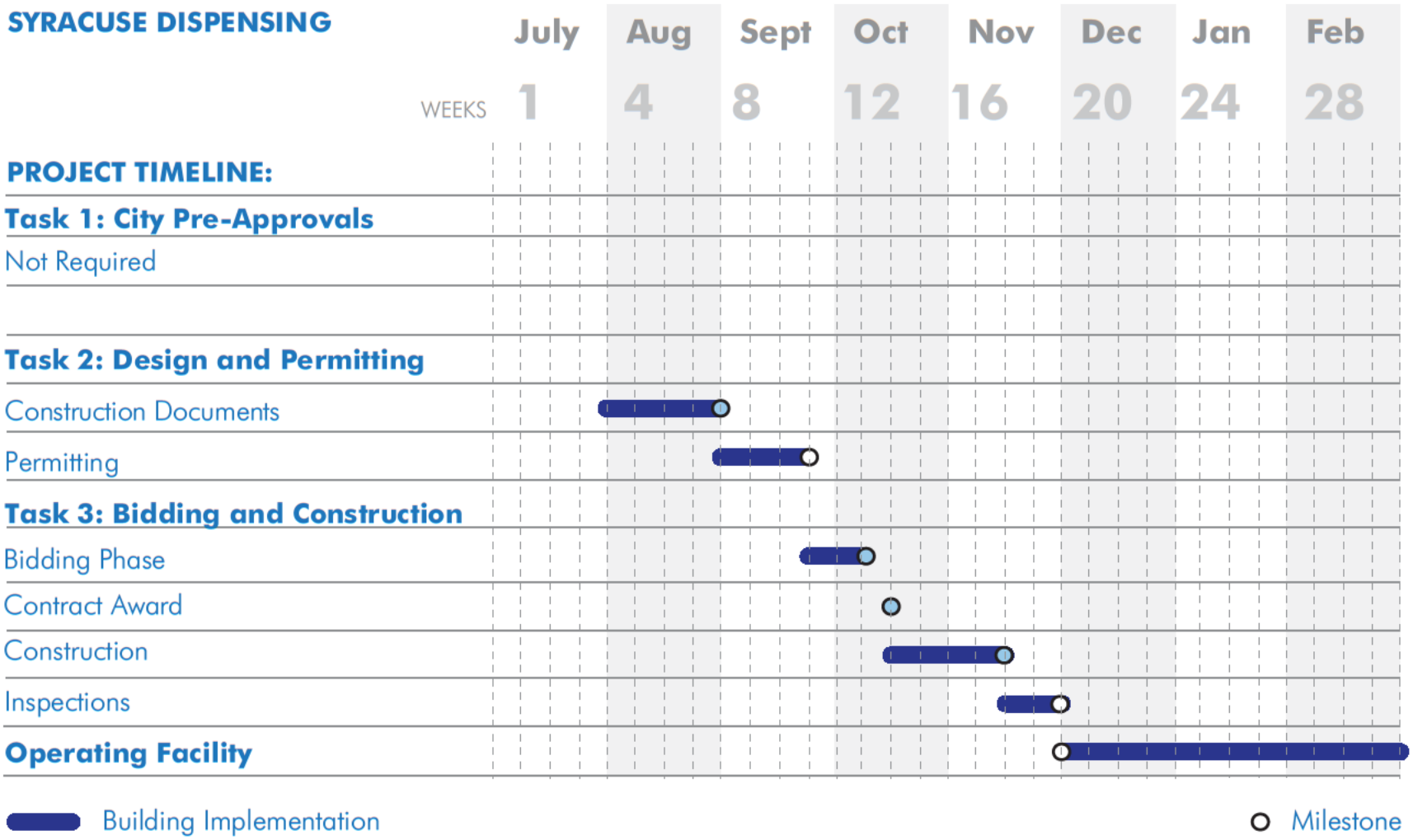
-Proficient in SAP and Documentum
-Hazmat Certified
-Experienced in 'Lean Manufacturing' techniques

Publications

Davies, H. M. L.; Panaro, S. A. Effect of Rhodium Carbenoid Structure on Cyclopropanation Chemoselectivity. *Tetrahedron* **2000**, *56*, 4871-4880.

Davies, H. M. L.; Hansen, T.; Hopper, D. W.; Panaro, S. A. Highly Regio-, Diastereo-, and Enantioselective C-H Insertions of Methyl Aryldiazoacetates into Cyclic *n*-Boc-Protected Amines. Asymmetric Synthesis of Novel C_2-Symmetric Amines and *threo*-Methylphenidate. *J. Am. Chem. Soc.* **1999**, *121*, 6509-6510.

Davies, H. M. L.; Panaro, S. A. Novel Dirhodium Tetraprolinate Catalysts Containing Bridging Prolinate Ligands for Asymmetric Carbenoid Reactions. *Tetrahedron Lett.* **1999**, *40*, 5287-5290.


SYRACUSE DISPENSING
July
Aug
Sept
Oct
Nov
Dec
Jan
Feb
WEEKS
1
4
8
12
16
20
24
28
PROJECT TIMELINE:
Task 1: City Pre-Approvals
Not Required
Task 2: Design and Permitting
Construction Documents
Permitting
Task 3: Bidding and Construction
Bidding Phase
Contract Award
Construction
Inspections
Operating Facility
Building Implementation
Milestone

Appendix B: Architectural Program

A SEPARATE "APPENDIX B" SHALL BE COMPLETED FOR EACH SEPARATE BUILDING AND/OR FACILITY INCLUDED IN THE ORGANIZATION'S BUSINESS PLAN

COMPANY INFORMATION	
Business Name:	Kinex Supportive Pharmaceuticals
Facility Type:	Manufacturing Facility ☐ Dispensing Facility ☑
Use and Occupancy Classification:	Mechantile
Building Construction Type and Classification:	IIb
Facility Address:	2320 Court Street, Syracuse NY 13208
Primary Contact Telephone number:	Jody Miller, MBA (716)440-0192
Primary Contact Fax number:	

PART I – ARCHITECTURAL PROGRAM & CONSTRUCTION TIMELINE:
Applicant shall identify planning requirements, including but not limited to:

☐	TOWN BOARD APPROVAL
☐	PLANNING BOARD APPROVAL
☐	ZONING BOARD OF APPEALS APPROVAL
☑	PREPARATION OF CONSTRUCTION DOCUMENTS
☑	BUILDING PERMIT
☑	BIDDING PHASE
☑	CONTRACT AWARD PHASE PER EACH APPLICABLE CONTRACTOR (Identify all that apply)
☑	COMMENCEMENT OF CONSTRUCTION
☑	COMPLETION OF CONSTRUCTION

Appendix B – Architectural Program

PART II – SITE PLAN(S)

Applicant shall provide the appropriate details for each of the following by identifying the location and dimension on the Site Plan attached to the application for each building location.

	☑ Entrance and Exits ☑ Public Parking Spaces ☑ Staff Parking Spaces ☑ Accessible Parking Spaces ☑ Accessible Route(s)	☑ Fire Lane and/or Fire Apparatus Road ☑ Percentage of Green Space ☑ Location of Emergency Power Systems ☑ Loading & Unloading ☐ Security Gates & Fences

PART III – ENERGY SOURCES & ENGINEERING SYSTEMS:

Applicant shall provide the following minimum information to outline the specifications relating to the energy sources and engineering systems of each building included in the application.

Energy Source:

☑ Natural Gas ☐ Oil ☑ Electric
☐ Solar ☐ Other _____

Engineering Systems:

☑ Heating System: Type pkg RTU, Size _____ Efficiency _____,
Ventilation Requirements per ashre standars

☑ Cooling System: Type pkg RTU, Size _____ Efficiency _____,
Ventilation Requirements per ashre standards

☑ Ventilation & Humidification Systems:
Type pkg RTU, Size _____, Efficiency _____,
Ventilation Requirements per ashre standards

☑ Electrical Distribution Available 480/277 volt

☑ Water Supply: Municipal Water Service x or Private Well Water _____

☑ Sewage: Municipal Sewer System x or Private Septic System _____

☑ Emergency Power System:
Type battery, Size varies Efficiency _____,

Appendix B – Architectural Program

PART IV – BUILDING CODE COMPLIANCE: (pages 3-13)	
CHECK ALL APPLICABLE CODES FOR THE FACILITY	
☑	2010 BUILDING CODE OF NYS
☑	2010 FIRE CODE OF NYS
☐	2010 PLUMBING CODE OF NYS
☐	2010 MECHANICAL CODE OF NYS
☐	2010 FUEL GAS CODE OF NYS
☑	2010 PROPERTY MAINTENANCE CODE OF NYS
☐	2010 ENERGY CONSERVATION CONSTRUCTION CODE OF NYS
☐	2012 IECC COMMERCIAL PROVISIONS
☑	2010 EXISTING BUILDING CODE OF NYS
☑	NEC NATIONAL ELECTRIC CODE, (Specify Applicable Version)
☐	2014 NY CITY CONSTRUCTION CODE
☐	2008 NY CITY CONSTRUCTION CODE
☐	1968 NY CITY CONSTRUCTION CODE
☑	NFPA 101-06 LIFE SAFETY CODE
☑	ICC/ANSI A117.1-03 ACCESSIBLE AND USABLE BUILDINGS AND FACILITIES
☐	OTHER

Appendix B – Architectural Program

Select Project Type: Check all that apply. Refer to the Existing Building Code for definitions.	☐ New Building ☐ Repair ☐ Alteration Level 1 ☑ Alteration Level 2	☐ Alteration Level 3 ☐ Change of Occupancy ☐ Addition ☐ Historic Building	☐ Demolition ☐ Chapter 3. Prescriptive Compliance Method ☐ Chapter 13. Performance Compliance Method
Select Work Involved: Check all that apply.	☑ General Construction ☐ Roofing ☐ Asbestos Abatement/Environmental ☑ Fire Alarm	☐ Structural ☐ Mechanical ☑ Plumbing ☑ Electrical	☑ Site Work ☐ Sprinkler ☐ Elevators ☐ Other:_____

CODE COMPLIANCE REVIEW

Applicant shall provide all applicable information in regards to the code topic and section listed below.

1. Code Compliance Review is based on the 2010 NY State Building Code for New Construction. If any other building code applies to the location or type of construction, provide applicable code and sections that most closely relates and references the code topic and information in the code sections listed below. Provide appropriate abbreviations for other applicable codes, such as: **FC:** ***Fire Code*****, PC:** ***Plumbing Code*****, MC:** ***Mechanical Code*****, FGC:** ***Fuel Gas Code*****, ECCC:** ***Energy Conservation Code.***
2. Provide the Required standard for each applicable code section. (i.e.: area, quantity, classification type, materials, hourly separation, etc.). If section does not apply, indicate one of the following with explanation: **NA:** *Not Applicable*, **NR:** *Not Required*, **NP:** *Not Permitted*
3. Provide your facilities "Actual" value for each required standard as per applicable code section.

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
1	Use & Occupancy Classification	302.1 - 312		Use & occupancy of this facility. Identify all applicable materials, class and quantities regarding Table 307.1.	M Mercantile	M Mercantile

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
2	Combustible Storage	413		All combustible storage areas and rooms, as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
3	Hazardous Materials	414		All hazardous materials stored or used as per applicable Building and Fire Codes. Identify all combustible stored materials, area and room dimensions, all required fire separations, and exit requirements.	NA	
4	Hazardous Materials Control Areas	414.2		Provide additional information indicating number, size, materials stored, and quantity of each material.	NA	
5	Building Area & Height	501-507		Provide the building area & height Provide all calculations and cite applicable code sections for increased Building Area & Heights allowed per building code(s).	existing building, section does not apply	
6	Incidental Use Areas	508.2		Identify all Incidental Use Areas and required fire separation of occupancies on Building Plans.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
7	Mixed Occupancies	508.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
8	Nonseparated Uses	508.3.2		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
9	Separated Uses (Ratio < 1)	508.3.3		Provide analysis with code cited, and required fire separation of occupancies. Identify required fire separation of occupancies on Building Plan(s).	NA	
10	Construction Classification	602		Provide Construction Classification per each building included in Application.	Type IIb	Type IIb
11	Fire Resistance Rating Reqm't for Building Elements	Table 601		Provide Fire Resistance Rating per each building element as per Table 601. Identify rating & elements on Building Plans.	not required	none provided

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
12	Exterior Wall Fire-Resistance Rating	Table 602		Identify required fire resistance rating of exterior walls on Building Plan(s).	NA	
13	Exterior Fire Separation Distance	Table 602		Identify required fire separation distance of exterior walls between Buildings on Plan.	existing building, section does not apply	
14	Fire Walls	705		Provide code information and identify all applicable required Fire Wall(s) and fire resistance requirement on Building Plans.	NA	
15	Fire Barriers	706		Provide code information and identify all applicable required Fire Barrier(s) and fire resistance requirement on Building Plans.	2 hr fire barriers required between fire areas	provided in tenant seperations
16	Shaft Enclosures	707		Provide code information and identify all applicable required Shaft Wall(s) and fire resistance requirement on Building Plans.	2 hr shaft enclosures required	see plans
17	Fire Partitions	708		Provide code information and identify all applicable required Fire Partition(s) and fire resistance requirement on Building Plans.	1 hr fire partitions required	see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
18	Horizontal Assemblies	711		Provide code information and identify all applicable required Horizontal Assemblies and fire resistance requirement on Building Plans.	Not Required	
19	Fire Protection: Sprinkler System	903		Indicate Type of Sprinkler System: ☑ NFPA 13 ☐ NFPA 13 R ☐ NFPA 13D Provide code information of all applicable requirements for Automatic Sprinkler Systems with code section cited.	Not required under 12,000sqft	fire area under 12,000sqft
20	Alt. Fire Extinguishing System	904		Provide code information of all applicable requirements for Alternative Automatic Fire-Extinguishing Systems with code section(s) cited.	NA	
21	Standpipe System	905		Provide code information of all applicable requirements for Standpipe Systems with code section(s) cited.	NA	
22	Fire Alarm & Detection Systems	907		Provide code information of all applicable requirements for Fire Alarm System(s) with code section cited. Indicate Type of Fire Alarm System ☐ Addressable ☑ Hardwired (zoned)	required with occupant load over 500	occupant load is less than 500 therefore its not required

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
23	Emergency Alarm System	908		Provide code information of all applicable requirements for Emergency Alarm Systems with code section cited.	NA	
24	Fire Department Connections	912		Identify Fire Department connections in accordance with NFPA applicable standard.	NA	
25	Exits	1001.1 &2		Identify on the Building Plans and documents, per each door, the following information: door width, door height, direction of swing, type of construction, hourly rating, and door closures.	required	provided, see plans
26	Occupant Load	1004 & Table 1004.1.1		Identify the use/name of each room, dimensions of each room, and Occupant Loads per each room on the Building Plans.	total occupant load is 25	see plans for occupant loads of individual spaces
27	Egress Width	1005		Provide egress widths & cite applicable code section(s) and requirement(s) on the Building Plans	stairways .3 per occupant, other components .2	stairways 8" other 5"
28	Accessible Means of Egress	1007.1		Provide accessible means of egress as per Section 1007 & cite applicable code section(s) and requirement(s) on the Building Plans.	required	provided, see plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
29	Doors, Gates, and Turnstiles	1008		Means of egress doors shall meet the requirements of this section.	required	Provided, See plans
30	Interior Stairs	1009		Identify the following information for each stairway on the Building Plan(s): the width of stairways; the height, width, depth and number of risers and treads; dimensions of landings; stairway construction type; and handrail height.	required	See plans
31	Ramps	1010.1		Identify the following information of each ramp, on the Building Plan(s): width; total vertical rise; length of ramp; and handrail height.	NA	
32	Common Path of Travel	1014.3		Identify on the Building Plan(s): the length of the "Common Path of Travel" per each room as per applicable building code requirements.	not greater than 75'	See plans
33	Exit Doorway Arrangement	1015		Identify on the Building Plan(s): applicable building code requirements for all Exits and Exit Access Doorways per each room and required exits in all buildings.	maximum occupant load with one means of egress is 49 people per space	See plans
34	Corridor Fire Rating	1017.1		Identify, on the Building Plan(s): all corridors with required fire resistance and the applicable fire rating.	1 hr fire resistance rating required in corridors	1hr provided See plans

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
35	Corridor Width	1017.2		Identify on the Building Plan(s): the width of all corridors. Provide applicable code section(s) and requirement(s).	44" min required	45" provided
36	Dead End Corridor	1017.3		Corridors shall not exceed the maximum dead end corridor length as per applicable code.	shall not exceed 20'	none provided
37	Number of Exits and Continuity	1019		Identify on the Building Plan(s): required number of exits, continuity and arrangement as per the applicable code requirements.	1 exits required	2 exits provided
38	Vertical Exit Enclosures	1020		Identify on the Building Plan(s): all applicable code requirements for each Vertical Exit Enclosure.	NA	no vertical exit enclosures
39	Exit Passageways	1021		Identify on the Building Plan(s): all applicable code requirements for each Exit Passageway.	required	Provided
40	Horizontal Exits	1022		Identify on the Building Plan(s): all applicable code requirements for each Horizontal Exit.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
41	Exterior Exit Ramps & Stairways	1023		Identify on the Building Plan(s): all applicable code requirements for each exterior exit ramps and stairways.	NA	no exterior stairs or ramps are provided in the project
42	Exit Discharge	1024		Identify on the Building Plan(s): all applicable code requirements for each Exit Discharge.	required	provided, see plans
43	Accessibility	1101.1 - 1110 & ICC/A117. 1(03)		Identify on the Building Plan(s): all applicable code requirements such that the design and construction of each building/facility provides accessibility to physically disabled persons.	required	provided, see plans for door and fixture clearances
44	Energy Conservation	2010 NYS ECCC & IECC 2012		Identify the R-Value and U-Value of each construction component and assembly of the building envelope as required in the applicable energy and building code(s).	existing building, section does not apply	
45	Emergency & Standby Power	2702.1		Identify emergency & Standby Power locations and specifications of the system to be provided.	NA	
46	Smoke Control Systems	2702.2.2		Identify the Standby power for smoke control systems in accordance with Section 909.11 of NYS Building Code.	NA	

Appendix B – Architectural Program

No.	Topic	NYS Building Code Section	Other Code[1] (as Stated Above) & Section	Minimum Information Required to be Identified for this building/facility on the Building or Site Plan(s)	Required Code Value[2] /Allowed Code Value	Facility's Actual Value[3]
47	Plumbing Fixture Count	2902.1		Identify on the Building Plan(s): the minimum plumbing facilities as per applicable plumbing code(s).	1 DF, 1 service sink, 1 WC M, 1WC F, 1Lav M, 1Lav F	1 DF, 1 service sink, 1 WC M, 1WC F, 1Lav M, 1 Lav F
48	Available Street Water Pressure			Provide the available street or well water pressure.	existing building, TBD	
49	Fire Apparatus Access Road	FC503.1		Identify on the Site Plan: Fire Apparatus Road, Fire Lane and other Fire Service requirements per applicable Building and Fire Codes.	see site plan	see site plan

June 1, 2015
Kinex Supportive Pharmaceuticals,

In order to comply with the Compassionate Care Act application, proof of internet access from a local service provider is needed. More specifically, attachment K calls for proof that all applicants' manufacturing and dispensing facilities are located in an area with internet connectivity. For the dispensary location at 2320 Court St. Syracuse, NY 13206. Verizon has services HSI & Hicap services available in the area [HSI is High Speed Internet (DSL) – with speeds ranging from 25/25 mbps to 300/300 Mbps

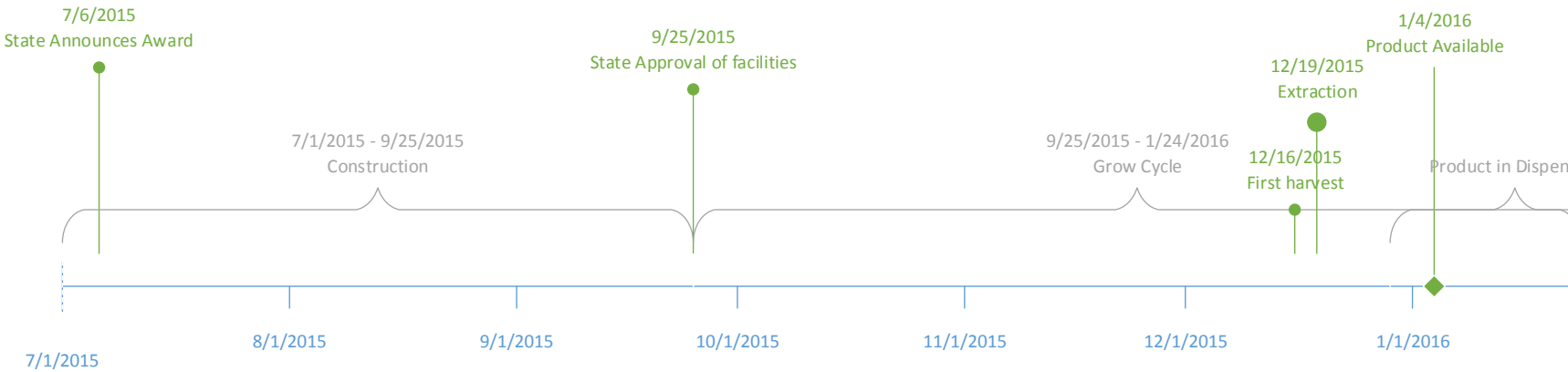
Sincerely,

J. Considine

John Considine
Network Engineering and Operations 6360
Thompson Rd, 02 Floor Syracuse, NY USA
13206
315-459-5082 W
[redacted]

Kinex Supportive Pharmaceuticals

Timeline Demonstrating Estimated Timeframe From Growing To Production of Final Approved



Dependencies

Testing Timelines for Wadsworth lab is less than 2 weeks

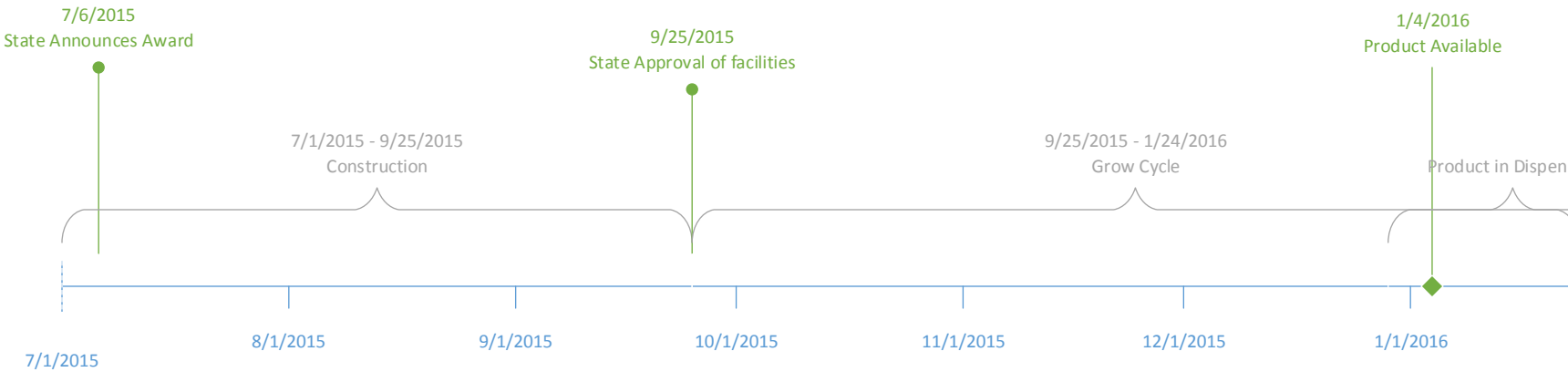
Extraction accelerated secondary to our freezing method vs drying

Tab 4

Location of Non Refundable and Conditionally Refundable Registration Fees

In the original application, the checks for the required fees appear in Tab 1 immediately behind the application's letter of introduction. In all copies of the application, copies of the checks for the application fees have been inserted in Tab 1.

Kinex Supportive Pharmaceuticals
Commitment to the Timeline



Kinex Supportive Pharmaceuticals
Timeline Commitment