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A. Nature of registration:

- Manufacturer/wholesaler Yes No Wholesaler only Yes No
- Repacker/wholesaler Yes No Medical gas repackager Yes No

B. Daily schedule of hours the establishment will be opened. (list days of week and hours opened.)

C. List percent of business done with the following (must equal 100%):

Domestic _____ % Foreign _____ %

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Check ALL items distributed at this location.

- Prescription required drugs (human) Medical Devices Prescription required drugs (animal)
- Hypodermic syringes and needles Controlled substances Compressed medical gases/liquid
- Over the counter drugs Cosmetics
- Other _____

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Building/Space Requirements

Has the following been adequately provided for? (check yes or no)

- Adequate lighting Yes No
- Appropriate sanitation Yes No
- Adequate space Yes No
- Necessary equipment Yes No
- Appropriate security Yes No
- Secure quarantine area Yes No
- Orderly stock control Yes No
- Free from insects, rodents, birds or vermin Yes No
- Drug areas secure from unauthorized entry Yes No
- Outside access well controlled and kept to a minimum Yes No
- Outside perimeter well lighted Yes No
- Alarm system for after hours Yes No
- Security system against theft and diversion Yes No
- Computer and electronic system security against theft and diversion Yes No
- Temperature control Yes No
- Humidity control Yes No
- Written policies and procedures for distribution/recalls etc. Yes No
- Hot and cold running water Yes No

Recording equipment used for temperature/humidity (check each):

- Manual Yes No
- Electromagnetic Yes No
- Electronic Yes No

Neighborhood (check type):

- Commercial Yes No
- Residential Yes No
- Both Yes No

Pharmacy Guide to Practice, Reference books, etc. Yes No

FOR MANUFACTURERS AND REPACKERS ONLY

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Supervision

Will all manufacturing and/or repacking be done under the personal supervision of a licensed pharmacist? Yes No

Supervisor's who are not pharmacists shall meet the requirements as outlined in Section 63.6 (c)(1) of the regulations for registration and operation and of the establishments.

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Do you have storage or manufacturing facilities for drug products at an address other than that indicated? Yes No

If your answer is "Yes," indicated locations and explain:

PART II

- Draw to scale the proposed establishment, indicating all dimensions. Show all doors and walls.
- Indicate areas for storage of drugs (drug bays).
- In red pen, indicate **R for refrigerator**.
- In red pen indicate **S for sink** that is located in the compounding and dispensing area.
- Outline the registered area in yellow.
- Indicate the premises adjacent to the buildings, offices and public thoroughfares.
- Name the adjacent businesses.
- **DO NOT SEND A BLUEPRINT, IT WILL BE DISCARDED.**

1 Total registered area _____ sq. ft.

2 Indicate Scale _____ sq. ft.

A large grid for drawing the proposed establishment. The grid consists of 30 columns and 30 rows of small squares, providing a scale for the drawing.

PART III

Contact person to clarify information provided on this application:

Name: _____

Phone: _____

Fax: _____

Email address: _____

PART IV: ATTESTATION

I affirm that all information submitted to the Board of Pharmacy is true. I am familiar with the Pharmacy Guide to Practice and the laws which govern the distribution of drugs and/or devices in New York State and with the Title 21 Code of Federal Regulations Part 205. I further understand that manufacturers, repackers and wholesalers may only sell drugs and/or devices to those purchasers authorized by law to receive them, and that records of the receipt and disposition of all drugs and/or devices shall be maintained for a period of five years and shall be available to the Department or any other authorized State or Federal agency for a period of not less than five years.

*Signature of applicant (Individual owner, partner, corporate officer, or *other authorized person)*

Date

Print Name

Date

*Power of attorney must be submitted for "other authorized person"

PART V: INSPECTION

Investigator's Comments:

Signature – Investigator Office of Professional Discipline

Date

Print name