OUTSOURCING FACILITY INFORMATION FORM

The University of the State of New York
THE STATE EDUCATION DEPARTMENT
Office of the Professions
State Board of Pharmacy
www.op.nysed.gov/pharm/

REGISTRATION NUMBER: _____

PART I **(Print in Black Ink)**

1 **Name of owner/corporation under which registration has been issued or is sought:**

2 **Trade Name (if applicable):**

3 **Outsourcing Facility Address:**

Street and Number

City

State County

Zip Code

4 **Complete ONE of the Following:**

A. ☐ **New Registration** **Proposed date of opening:** mo . day yr.

B. ☐ **Transfer of Ownership** **Proposed date of transfer:** mo . day yr.

Name of previous registrant: _____

Registration number:

C. ☐ **Change of location** **Proposed Date of change:** mo . day yr.

Previous address: _____

D. ☐ **Renovation** **Proposed date of renovation:** mo . day yr.

E. ☐ **Update/Other** _____

5 **Has the applicant applied for or been issued registration at any other location in this state by this department?** ☐ **Yes** ☐ **No**

If yes, please list the address and registration number. Use additional paper if necessary.

_____ _____
Location and Address Registration Number

Does this applicant have a New York State registered pharmacy? ☐ Yes ☐ No

6 **List Supervisor of this establishment**

_____

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

_____

8 Will this facility compound products on the FDA's drug shortage list? ☐ Yes ☐ No

Will this facility compound products from bulk drug substances? ☐ Yes ☐ No

If yes, will these be sterile drugs? ☐ Yes ☐ No

9 **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

Reference books, etc. ☐ Yes ☐ No

10 Date of most recent FDA inspection: _____ / _____ / _____
mo. day yr.

Will this location also be registered as a pharmacy? ☐ Yes ☐ No

11 **Supervision**

Will all compounding be done under the personal supervision of a licensed pharmacist? ☐ Yes ☐ No

12 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.**

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 laws, rules and regulations 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

Return Directly to: New York State Education Department, Office of the Professions, State Board of Pharmacy, 89 Washington Avenue, Albany, NY 12234-1000