

License Application to Engage in a Controlled Substance Activity

****PLEASE PRINT OR TYPE****

APPLICANT INFORMATION			CONTACT INFORMATION	
Legal Name			Name	
d/b/a			Title	
Street *			Telephone	
City			Fax	
State	Zip	County	E-Mail	
Controlled Substance License #			* If using a PO Box, a street address must be included.	

APPLICATION TYPE		
<input type="checkbox"/> NEW	Note: New applicants and those reporting a relocation or a change in ownership will be subject to an on-site facility inspection (excluding out-of-state applicants).	Date proposed for controlled substance activity to begin. ____/____/____
<input type="checkbox"/> Name Change	Prior Name: New Name:	
<input type="checkbox"/> Address Change <input type="checkbox"/> Postal Only <input type="checkbox"/> Relocation	Prior Address: New Address:	
<input type="checkbox"/> Ownership Change	Prior Owner(s): New Owner(s):	
<input type="checkbox"/> RENEWAL	<input type="checkbox"/> No Change since most recent license	
<input type="checkbox"/> AMENDMENT	Attach narrative outlining change(s) requested.	

LICENSE CLASSIFICATION (check only one box)	New License/ Renewal Fee	Amendment Fee	Office Use Only	
<input type="checkbox"/> Class 1 Manufacturer	\$1200	\$250	Cashline:	
<input type="checkbox"/> Class 1a Manufacturer (Out-of-State)	\$1200	\$250	<input type="checkbox"/> Approved ____/____/____	
<input type="checkbox"/> Class 2 Distributor	<input type="checkbox"/> Check if Reverse Distributor	\$1200	\$250	<input type="checkbox"/> Other ____/____/____
<input type="checkbox"/> Class 2a Distributor (Out-of-State)	<input type="checkbox"/> Check if Reverse Distributor	\$1200	\$250	Comment(s) _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
<input type="checkbox"/> Class 3 Institutional Dispenser	Operating Certificate #	\$100	N/A	
<input type="checkbox"/> Class 3a Institutional Dispenser Limited	Operating Certificate #	\$100	N/A	
<input type="checkbox"/> Class 4 Researcher (Schedules II-V)	<input type="checkbox"/> Individual <input type="checkbox"/> Institutional	\$40	\$20	
<input type="checkbox"/> Class 5 Instructional Activities (Schedules II-V)		\$40	\$20	
<input type="checkbox"/> Class 7 Research/Instructional (Schedule I)	<input type="checkbox"/> Individual <input type="checkbox"/> Institutional	\$40	\$20	
<input type="checkbox"/> Class 8 Analytical Laboratory		\$40	\$20	
<input type="checkbox"/> Class 9 Importer		\$1200	\$250	
<input type="checkbox"/> Class 9a Importer Broker		\$1200	\$250	
<input type="checkbox"/> Class 10 Exporter		\$1200	\$250	
<input type="checkbox"/> Class 10a Exporter Broker		\$1200	\$250	
<input type="checkbox"/> Class 11 Pharmacy - Automated Dispensing System (ADS)	NO FEE	N/A	Reviewer: _____	

- ✓ New York State, county and municipal agencies are **exempt** from licensing fees.
- ✓ Applicants registered with the New York State Board of Pharmacy (BOP) must submit a copy of their registration.
- ✓ Applicants registered with the Drug Enforcement Administration (DEA) must attach a copy of their registration.
- ✓ Class 1, 1a, 2, 2a, 9, 9a, 10 and 10a applicants must list all Schedule I controlled substances to be manufactured, distributed, imported and/or exported.
- ✓ Class 1, 1a, 2 and 2a applicants must provide the name, residential address, and title of each officer, director and any person having 10% or greater proprietary, beneficial, equitable or credit interest in the applicant.
- ✓ Class 3 and 3a applicants must **submit a copy** of their current authority to operate (i.e., Operating Certificate) issued by the Department of Health or other State agency.
- ✓ Class 4, 5, 7 and 8 applicants must submit specific information consistent with Sections 3325 and 3326 of the Public Health Law (see associated instructions).
- ✓ Class 11 Pharmacy – ADS applicants must submit a copy of their ADS policy.

CONTROLLED SUBSTANCE SCHEDULE(S) TO BE UTILIZED (check all that apply) I II III IV V**STORAGE OF CONTROLLED SUBSTANCES** (check all that apply)

<input type="checkbox"/> Vault	Describe
<input type="checkbox"/> Safe	Describe
<input type="checkbox"/> Cabinet	Describe
<input type="checkbox"/> Other	Describe
<input type="checkbox"/> Additional Security	Describe

SUPERVISOR OF CONTROLLED SUBSTANCE ACTIVITY

(complete only if an individual other than the applicant will be supervising controlled substance activity)

Name	Title
Signature	Type of Professional License and Number

APPLICANT ACKNOWLEDGEMENTS

The applicant fully understands that the license to be issued hereon shall be subject to the following stipulations and conditions:

1. The applicant is knowledgeable concerning all laws and regulations, both State and Federal, regarding the licensed activity and shall comply with such requirements.
2. The licensee shall be under a continuing duty to inform the Department of Health of any changes, such as name, address or any substantial change to the physical security and means of record keeping regarding the controlled substance(s).
3. The license privilege herein applied for, if granted, shall not be transferred. Changes in name or ownership of institutional and business licensees shall be immediately reported to the Department of Health.
4. Any license so issued as a result of the application for license shall be promptly returned to the Department of Health upon revocation or suspension of the license or the Federal license for the activity. The license shall be promptly returned to the Department of Health when the activity for which the applicant is licensed has been discontinued.
5. Licensee shall promptly report to the Department of Health each incident or alleged incident of theft, loss or possible diversion of either controlled substances or Official New York State Prescriptions. Such notification shall be by first contacting the local Regional Office of the Department of Health's Bureau of Narcotic Enforcement and then shall be reported on the applicable Department of Health forms. **Reporting of such incident to other government agencies does not relieve the applicant of this responsibility.**

Has the applicant or Supervisor of Controlled Substance Activity been convicted of an offense in any jurisdiction relating to any substance listed in PHL Article 33 as a controlled substance?

Has the applicant, its employees, subsidiaries, managing officers, or directors failed to comply with the provisions of the Federal Controlled Substance Act or the laws of any State relating to controlled substances?

 YES * NO

Has the applicant or Supervisor of Controlled Substance Activity ever had a State or Federal controlled substance license or registration or professional license or registration revoked, suspended, denied or restricted or been placed on probation?

 YES * NO**If the applicant is a partnership, stockholder, proprietor or corporation (other than a corporation whose stock is owned and traded by the public):**

Has the business, any officer or the Supervisor of Controlled Substance Activity been convicted, fined, censured or had a license (State or Federal) suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs?

 YES * NO

* Applicants who answer 'YES' to any of the above questions must submit a statement of explanation with documentation to support the explanation.

APPLICANT SIGNATURE (must be an original signature in ink)**Under the penalties of perjury, I affirm that the statements herein are true and that I have become knowledgeable regarding the requirements of the licensed activity for which I am applying.**

Name	Title
Signature of Applicant (or Authorized Representative)	Date

Return the completed application, all supporting documentation and the applicable fee (in the form of a check or money order made payable to the New York State Department of Health, Bureau of Narcotic Enforcement) to:

New York State Department of Health
Bureau of Narcotic Enforcement
Riverview Center
150 Broadway
Albany, New York 12204