

This form is to be completed for Class 1, 1A, 2 and 2A license applicants. 10 NYCRR Part 80.11 identifies the requirements for manufacturers and distributors of controlled substance for the supervision of their controlled substance activities.

Email completed form and supporting documents to bnlicensing@health.ny.gov

****PLEASE USE ADOBE TO FILL IN****

Entity Information				
Legal Name			Check Applicable Box <input type="checkbox"/> Manufacturer <input type="checkbox"/> Distributor	
d/b/a			BNE License Number, If Licensed	
Street			DEA Registration Number	
City			State Licensed In	
State	ZIP	County	Home State License Number	NYS BOP Registration Number
Facility Representative Contact Information				
Name			Title	
Telephone		Fax	Email	
Supervisor of Controlled Substances Applicant				
Name			Title	
Home Street Address			City	
State	ZIP	Phone	Email	
Manufacturer Supervisor Requirements				
<p>A class 1 manufacturer who produces a final product that by its composition or combination with other ingredients is not intended for human or animal consumption and does not present a potential for abuse, must employ either a full-time pharmacist or a full-time chemist and the licensed activity in which he or she is engaged must be under the supervision of either a pharmacist, or a chemist, as defined in subdivision (a) of this section. The supervisor shall not be at the same time a supervisor of any other class 1 or class 2 establishment licensed by the New York State Department of Health.</p> <p>A class 1 manufacturer who produces a final product that by its composition or combination with other ingredients is intended for human or animal consumption and presents a potential for abuse, must employ a full-time pharmacist and the licensed controlled substance activity must be under the personal supervision of a pharmacist or a chemist. The supervisor shall not be at the same time a supervisor of any other class 1 or class 2 establishment licensed by the New York State Department of Health. A chemist is a person who meets the following requirements:</p> <p><i>(Submit copies of all documents with this form for applicable section.)</i></p>				
Applicant Initials	FULL-TIME PHARMACIST			
	Home state pharmacist license or registration			
	NON-PHARMACIST/CHEMIST SPECIFIC REQUIREMENTS			
	Possess a Bachelor of Science or a Bachelor of Arts degree in chemistry, pharmacology or equivalent specialization and have had not less than four years of experience in the manufacture of drug products			
	Be a citizen of the United States or an alien lawfully admitted for permanent residence in the United States			
	Be of the age of 21 years or older			
	Be of good moral character and, if the person has been convicted of one or more criminal offenses, he or she must be found eligible after a balancing of the factors set out in Article 23-A of Correction Law. In accordance with that Article, no person shall be deemed not to be a chemist on account of having been previously convicted of one or more criminal offense unless (i) there is a direct relationship between one or more of the previous criminal offenses and the duties required of the position or (ii) deeming the person a chemist would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public. In addressing these questions, the Department shall evaluate all factors listed under New York State Correction Law Section 753			
	Not be, and not have been, a habitual user of narcotics or any other habit-forming drugs			
Distributor Supervisor Requirements				
<p>An applicant for licensure who is a registered wholesaler pursuant to Title 8 of the Education Law who bottles or rebottles, packs or repacks, labels or relabels, controlled substances shall be deemed as conducting class 1 manufacturing activities of controlled substances and subject to the requirements above.</p> <p>An applicant for licensure who is a registered wholesaler pursuant to Title 8 of the Education Law who does not bottle or rebottle, pack or repack, label or relabel, controlled substances may obtain a class 2 distributor license, provided that the licensed activity in which he or she is engaged is conducted under the personal supervision of a pharmacist or a person approved by the Department. The supervisor shall not be at the same time a supervisor of any other establishment registered by the New York State Board of Pharmacy. A person not a pharmacist shall meet the following requirements:</p>				

Applicant Initials	PHARMACIST
	Home state pharmacist license or registration
	NON-PHARMACIST SPECIFIC REQUIREMENTS
	Possess a high school diploma, or the equivalent thereof
	Be a citizen of the United States or an alien lawfully admitted for permanent residence in the United States
	Be of the age of 21 years or over
	Be of good moral character and if the person has been convicted of one or more criminal offenses, he or she must be found eligible after a balancing of the factors set out in Article 23-A of Correction Law. In accordance with that Article, no distributor license shall be denied by reason of the applicable employee having been previously convicted of one or more criminal offenses unless (i) there is a direct relationship between one or more of the previous criminal offenses and the duties required of the license or (ii) licensing the applicant would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public. In determining these questions, the agency will look at all factors listed under New York State Correction Law Section 753
	Not be, and not have been, a habitual user of narcotics or other habit-forming drugs
	Have had not less than eight years of experience in the wholesaling of controlled substances, or such other experience determined by the Department to be the equivalent thereof (submit written justifications and qualifications for such other experience to be reviewed by the Department)

Supervisor Responsibilities

An individual who is designated as the supervisor of controlled substance activity pursuant to Part 80.11 subdivisions (a), (b) or (c) of this section shall be responsible for the following non-delegable tasks:

1. maintaining all required records relating to the purchase and distribution of all controlled substances manufactured or repacked at that facility;
2. providing for the proper storage of controlled substances in order to prevent loss or theft;
3. assuring security and limiting access to all areas holding controlled substances;
4. insuring against all unauthorized sales or distribution of controlled substances to establishments or professionals not authorized to receive such items;
5. issuing verbal and written notice to each of his or her subordinates concerning the applicable state and federal laws, regulations and rules to ensure full compliance;
6. for manufacturers, assuring that all Good Manufacturing Procedures as outlined by the FDA are followed; and
7. for manufacturers engaged in compounding of controlled substances, assuring that all controlled substances are compounded under the personal supervision of a licensed pharmacist.

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 applicant 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. 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 contacting the Central 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.**
4. Applications are valid for 90 days from date of receipt. After 90 days, if application is not approved or denied for licensure, the application will be deemed insufficient. Applicants may reapply, if they so choose, by submitting a new application.

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

All required documents reflecting applicable requirements and copies of appropriate license or registrations have been attached and submitted with this form.
 YES* NO

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

Supervisor Applicant Signature

Under the penalties of perjury, I affirm that the statements herein are true, to the best of my knowledge, and that I am knowledgeable regarding the requirements of the licensed activity for which I am applying.

Name	Title
Signature of Applicant	Date

Notary Public

Affirmation and Acknowledgment of Supervisor Applicant

Notary Stamp	Notary Signature
	Date