



NEW YORK STATE BOARD OF PHARMACY

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The application to register a non-resident manufacturer, wholesaler or repacker in New York State is self-explanatory. All non-resident manufacturers, wholesalers and repackers doing business in New York State **MUST BE REGISTERED** with the New York State Board of Pharmacy.

The burden of submitting a properly completed application rests with the applicant. **Incomplete applications cannot be processed. They will be returned to you for completion. All required documents must be submitted with the application. Do not send separately.**

If you want the New York State Department of State to act as your resident agent, you must file for Authority to do Business in New York. They can be reached at 518-473-2492 or visit their website for information, instructions and forms [www.dos.state.ny.us/corp/corppwww.html](http://www.dos.state.ny.us/corp/corppwww.html).

Applications are processed in the order in which they are received. In the interest of fairness, we cannot deviate from this policy. Submit your completed application at least eight (8) weeks prior to your anticipated registration date. Retain at least one copy of all forms and documents submitted.

### Items to Submit for Registration of a Non-Resident Wholesaler/Manufacturer/Repacker

1. Completed Application form (4 pages). Notarized signature is required on Page 4.
2. If your corporation is using the NYS Secretary of State as registered agent, include a copy of the Official Filing Receipt for Authority to do Business in New York (question 12).
3. Letter of Certification/Verification of License/Permit/Registration in your RESIDENT State with Official Seal must be provided.
4. Application fee of \$825. **ONE** individual check per establishment is required. No fee is needed for change of location.
5. Copy of your current license/permit from your home state.
6. For Transfer of Ownership, a seller's certificate or Bill of Sale is required.
7. For **Manufacturers only**, also send a copy of:
  - Proof of registration with the FDA as a manufacturer or
  - Copy of FDA assigned drug labeler code
  - Recent FDA inspection report indicating the manufacturing facility has completed and passed FDA site visit
  - Copy of approval letter for New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologic License Application (BLA) for each new drug your facility anticipates manufacturing or a waiver from the FDA that states this is not necessary
  - "Virtual manufacturers" must provide the front and last page of the contract entered into with the contract manufacturer.

### Do you need to register?

- Manufacturers, repackers, or wholesalers must register to do business in New York State if they are selling, shipping, mailing, providing samples of, delivering or distributing prescription drugs or devices into New York State. This would be drugs and devices that indicate "**Rx Only**" or "**Federal Law prohibits dispensing without a prescription.**" Registration is also required of manufacturers, repackers, or wholesalers that invoice into New York State.
- The sale of catheters or other devices that have a caution label "**Federal Law prohibits dispensing without an order**" is an indication of a non-prescription device.  
Example: A catheter is **not** a prescription device.  
A contraceptive diaphragm **is** a prescription device.
- New York State Department of Health Regulations require needles and syringes to be dispensed as prescription devices in New York State. You may reference Department of Health Regulation 80 for pertinent information.
- **A wholesaler may not sell or distribute needles and syringes to an individual person in New York State. This is dispensing and requires an individual prescription.**

### Establishments Performing Isolated Transactions Do Not Have to Register

As defined in the Regulations governing New York State Non-Resident Pharmacy and Wholesaler registrations, establishments that meet the criteria of an "isolated transaction" are NOT REQUIRED TO REGISTER.

Isolated transaction means for pharmacies, 600 or fewer prescriptions per calendar year for drugs and/or other devices delivered into New York State, and for manufacturers and wholesalers, sales that total less than \$10,000 in value, at wholesale per calendar year, for drugs and/or devices delivered into New York State, except that upon application by a nonresident establishment, the department may deem a transaction to be an isolated transaction, when such transaction is necessary to protect the public health by addressing a temporary emergency shortage of a prescription drug and/or device in New York State.