Secretary of State
Office of Professional Regulation

PHARMACY
Renewal Instructions for Non-Resident Manufacturer

Includes Actual/Contract Manufacturers, Virtual Manufacturers, Repackagers and Relabelers.

In order to renew you will need to:

1. Submit an online renewal application and pay the non-refundable application fee. Renewal applications are found within the online licensing system at: https://secure.professionals.vermont.gov/prweb/PRServlet/app/default/ybVBleIGIHMlPa8qpM9BaiNEZfDPENuF*/!STANDARD

   All required documentation must be uploaded within the online services system. The office will not accept paper copies of documentation pertaining to renewal requirements.

   Be prepared to answer questions about the following and supply any related information/documentation, which includes but is not limited to:

   - Has there been an ownership or location change since this license was last renewed?
   - Has the entity shipped or arranged for shipment of drugs into Vermont within the past 2 years?
   - Has the facility conducted a recall for its products within the last 2 years?

2. **Submit an updated Trading Partners Form.** The term trading partners, within an application for licensure in Vermont, refers to other entities with which the applicant entity partners (either up or downstream) and are, therefore, part of the drug supply chain that results in prescription drugs entering Vermont. They include, but may not be limited to: virtual manufacturer/contract manufacturer and virtual distributor/full service wholesale distributor relationships; third-party logistics providers used by manufacturers and/or wholesalers to warehouse and/or transport drugs, etc. These entities are not limited to Vermont locations.

3. **Submit Inspection**: All entities must submit proof (i.e. full inspection report) that they have successfully passed and maintained an acceptable current inspection (not more than 3 years old).

   Acceptable inspections: FDA, NABP's Drug Distributor Accreditation (formerly known as VAWD) or State Board Inspection. Virtual Manufacturers without inspection requirements in your home state, upload verifying document from that state.

4. FDA Inspection questions:
   - Has this entity been inspected by the FDA within the past 2 years?
   - Was your entity issued a Form 483?
   - Was your entity issued an Untitled letter?
   - Was your entity issued a Warning Letter?
   - Was your entity subject to a seizure by the FDA?
   - Was your entity subject to an injunction by the FDA?
   - Has your firm received a request for a Regulatory Meeting with the FDA?

5. **Report changes in contact person**: If applicable, upload the Statement of Contact Person form and the signed and notarized Affirmation form.

NOTE: Any change of address or other contact information, by an applicant or licensee, must be forwarded to this office no later than thirty (30) days after change occurs.

Important Notes for Renewal

If your first license was issued within 90 days of the first renewal expiration date, your license is valid until the next renewal date. Please check the expiration date printed on your license.

Three (3) courtesy renewal reminders are sent to the email on file starting approximately 6 weeks prior to the renewal expiration date. It is your responsibility to ensure your email address is up to date. You may update your email by logging in to Online Licensing and updating your profile. Please check your spam folder and add our office to your safe senders list.