



**Secretary of State  
Office of Professional Regulation**

**PHARMACY**  
**Application Instructions for 503B Outsourcer**

1. Complete online application and pay the licensing fee (nonrefundable processing fees).  
Note: All signatures required on the application must be those of an Owner, a Partner, or Corporate Officer.
2. FDA Establishment Identifier Number to provide evidence that applicant 503B Outsourcer is duly registered with the FDA
3. List(s) of the names of all owners owning 5% or more of the corporation. Each owner listed will need to complete an Affirmation form. Note: Changes in ownership require submittal of a new application.
4. Provide a flow chart showing ownership. If an actual flow chart is not available, a description of the ownership or hierarchy of the organization is acceptable. Upload completed and notarized affirmation forms for each owner.
5. Upload statement of Supervising Pharmacist using the Pharmacist in Charge form.
6. If the entity is licensed in another state, contact your state's Board of Pharmacy or applicable licensing authority and request that a verification of good standing be sent directly to Vermont. If the state does not license this type of drug outlet, submit a statement from the State's Board of Pharmacy.
7. Provide information about FDA inspections, and actions issued, to your facility within the past 5 years.
8. Provide DEA registration information, if controlled substances will be shipped into Vermont.
9. Acknowledgement of whether the applicant/503B Outsourcer was subject to recall of its products within the past 2 years.
10. Submit a copy of current business registration as filed with the Vermont Secretary of State, Corporations Division. 802-828-2386.

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