

**INSTRUCTIONS FOR ANNUAL WHOLESALE DRUG
Manufacturer / (Reverse) Distributors / Warehouses Licenses**

North Dakota law requires all businesses operating in North Dakota to be registered with the North Dakota Secretary of State's office. If your business and/or corporation is not registered with the North Dakota Secretary of State's office, **please register your business prior to applying for a North Dakota Board of Pharmacy (NDOBPh) license.** If your dba name is different than your corporation name, the Office of the North Dakota Secretary of State also requires a trade name or fictitious name registration.

This link will take you to their information page: <http://www.nd.gov/sos/businessserv/registrations/index.html>
Their information page contains instructions and links to the appropriate application forms for your business location (in state or out of state) and structure.

North Dakota Century Code 43-15.3-01 subsection 17 says:

17. "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third-party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

Initial State-specific Requirements

Type of Wholesaler	Need to be registered with the ND Secretary of State's Office?	Need a North Dakota Board of Pharmacy License?	Need to be VAWD accredited?
Chain drug warehouses	Yes	Yes	Yes
Common carrier or one hired solely to transport prescription drugs	Possibly. Verify with the ND Secretary of State's Office.		
Distributor of non-prescription medications	Yes	Voluntary	No
Durable Medical Equipment (DME) Distributors	Yes	Voluntary	No
Independent Wholesale Drug Warehouses	Yes	Yes	Yes
Jobbers/Brokers	Yes	Yes	Yes
Manufacturers	Yes	Yes	No – if FDA approved Yes – if not FDA approved
Medical gas distributors	Yes	Yes	No
Own label distributors	Yes	Yes	Yes
Private label distributors	Yes	Yes	Yes
Repackagers	Yes	Yes	Yes
Reverse distributors	Yes	Yes	Yes
Third-party logistics providers	Yes	Yes	Yes
Veterinary supply company (animal only medications)	Yes	Yes	No
Wholesale distributors of legend drugs	Yes	Yes	Yes
All Others:	Yes		

This letter will clarify the information you need to provide for the enclosed Application. Please also see VAWD ACCREDITATION INSTRUCTIONS.

North Dakota Secretary of State System Identification # Please include the number on your North Dakota Certificate of Authority. If you are using a dba name, also include the number on your North Dakota Trade Name or Fictitious Name Certificate. Attach a copy of the certificate(s) to your application.

Federal Drug Enforcement Administration # Companies which manufacture or distribute controlled substances should include their DEA number on their application.

Type of Facility to be Licensed Please identify the function/ industrial classification of the facility to be licensed.

Manufacturers The manufacturer whose name appears on the product must furnish its FDA Establishment Identification Number if licensing the manufacturing location, or its FDA assigned labeler code if licensing a corporate office or other location which does not actually manufacture product. Manufacturers of controlled substances must also include their DEA number on the application.

Medical Gas Distributors must register with the North Dakota Secretary of State's Office and obtain a license from the North Dakota Board of Pharmacy, but are exempt from VAWD.

Veterinary Supply Companies which manufacture and/or distribute animal only medications must register with the North Dakota Secretary of State's Office and obtain a license from the North Dakota Board of Pharmacy, but are exempt from VAWD.

Durable Medical Equipment Distributors must register with the North Dakota Secretary of State's Office. Currently, licensure with the North Dakota Board of Pharmacy is voluntary.

Distributors of Non-Prescription Medications must register with the North Dakota Secretary of State's Office. Currently, licensure with the North Dakota Board of Pharmacy is voluntary.

All other firms engaged in the wholesale, manufacture, and distribution of pharmaceutical products should review the Initial State-specific Requirements Chart and VAWD Accreditation instructions. If your type of business is not listed, and you have any questions regarding licensure or application for a license, please call the North Dakota Board of Pharmacy.

All Renewal Applications must be IN our office by June 1st, 2010 or they will be considered late and a delinquent fee will be assessed. You can renew your application online at www.nodakpharmacy.com .

All questions about registration with the North Dakota Secretary of State should refer to www.nd.gov/sos/ where all of the Secretary of State information and application forms are available.

Complete applications will be processed as they arrive. If your application is incomplete, your license will not be issued until staff has had time to identify and verify the missing information.

If you are sending your application to the office any other way than regular 1st Class mail you MUST use the street address NOT the P O Box. [1906 E Broadway – Bismarck ND 58501]