



South Carolina Board of Pharmacy

110 Centerview Dr. • Columbia • SC • 29210

P.O. Box 11927 • Columbia • SC 29211-1927

Phone: 803-896-4700 • Contact: pharmacy@llr.sc.gov • Fax: 803-896-4596

llr.sc.gov/bop

**NON-RESIDENT WHOLESALE/DISTRIBUTOR PERMIT APPLICATION
REQUIREMENTS AND INSTRUCTIONS**

A Wholesale Distributor Permit is required for a facility to engage in wholesale distribution of prescription drugs and/or devices to permitted facilities and licensed practitioners. Entities requiring a Wholesale Distributor Permit include, but are not limited to: own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A South Carolina Wholesale/Distributor Permit Application has a one-year expiration. A Wholesale Distributor Permit is required for virtual wholesale distributors defined as a business entity that arranges for the distribution of a drug or device, with or without taking actual possession of the drug or device, and contracts with others for the distribution, purchase and sale.

If you are also a 3PL you will need to concurrently apply for a 3PL permit.

Regulations 99-43(G)(3)(b) requires the permit holder to appear before the Non-Resident Application Review Committee to answer questions about all aspects of the applicant's operations. This appearance shall be in lieu of an in-person inspection of the applicant's facility and is designed to provide the Board with information that would typically be obtained during an in-person inspection. **All requested information and emailed confirmation are required prior to the meeting date.**

Failure to complete all required fields and/or provide necessary supplemental documentation will delay the application process. If an item is not applicable, please indicate N/A. **In order to avoid delay, please do not provide the items below in a binder, folder or use dividers. Also, provide items in the order as listed below. Only use one side of paper. Please write legibly. Retain copies of everything you have provided.**

Include this checklist with your application (check N/A if not applicable):

Included N/A

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Check or money order only (no cash) in the amount of \$700 made payable to SC Board of Pharmacy. (Application fee is non-refundable. A returned check fee of up to \$30, or an amount specified by law, may be assessed on all returned funds.) |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of all operational inspection reports conducted within the last two years. |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of FDA inspection, any 483(s) issued, and applicant's response |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of FDA registration |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of current DEA registration |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of state controlled substance registration |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of policy and procedure for shipping refrigerated products and monitoring temperature and humidity |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of policy and procedure on security, disaster plans and storage |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of licensure from resident state |
| <input type="checkbox"/> | <input type="checkbox"/> | A letter describing, in detail, the nature of your business |
| <input type="checkbox"/> | <input type="checkbox"/> | Provide a list of all pharmacy permits/licenses and license numbers held in other states |
| <input type="checkbox"/> | <input type="checkbox"/> | Photographs of: <ul style="list-style-type: none">o Entranceo Exito Product Area |
| <input type="checkbox"/> | <input type="checkbox"/> | Include organizational chart from the ultimate parent company down to and including the applicant |
| <input type="checkbox"/> | <input type="checkbox"/> | If a change of ownership, include organization charts of before and after the change. Chart must include names of owners with a 10% or greater ownership interest if a non-publicly traded company. |

If you are a virtual wholesaler, also include the items below:

Included N/A

- Provide the name, address, and South Carolina permit number of all 3PLs and/or wholesale distributors you will be using. If available, provide the Drug Distributor accreditation certificate or a notarized letter certifying the facility is in compliance with NABP standards.



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NON-RESIDENT WHOLESALE/DISTRIBUTOR PERMIT APPLICATION

- Form options: New Facility, Change to Existing Permit, Change of Name, Change of Location, Change of Ownership

Table with 2 columns: For Board Use Only, Date Paid, Amount Paid, Check No.

Type of Activity (check all that apply):

- Wholesale/Distributor, Virtual Wholesale/Distributor, Broker

FACILITY INFORMATION

Federal Tax ID No.: NABP e-Profile ID No.: Resident State License No.:

Legal Facility Name:

DBA Name:

Facility Address:

City: State: Zip:

Telephone:

Is application based on a change in ownership? Yes No

If Yes: Previous Name of Facility SC Permit No.:

Name of Designated Representative: Phone No.:

Email for Designated Representative:

Mailing address where all correspondence regarding licensure will be mailed if other than facility above:

Contact Person: Email:

Facility Name:

Mailing Address: City: State: Zip:

- 1. Has your facility been inspected by the FDA?
2. If inspected by the FDA, was your facility issued a 483?
3. Are you currently shipping into South Carolina from this facility?
4. Which of the following entities do you sell/ship product to? Check all that apply: Pharmacies, Hospitals, Clinics/Surgical Centers, Wholesalers, Dentists, Physicians, Podiatrists, Government Agencies, Nursing Homes, Veterinarians, Optometrists, Other (specify):

5. Will the facility utilize a 3PL or wholesaler to distribute the product? Yes No

If yes, list all names and locations of distributors (attach additional sheets if necessary):

6. Type of products distributed. Check all that apply:

- Prescription Drugs Legend Devices OTC drugs
 Non-Legend Devices Controlled Substances

7. Does your facility have Drug Distributor Accreditation through NABP? Yes No

8. Have you ever applied for Drug Distributor Accreditation? Yes No

If yes, what is the status of the application? _____

9. Is this facility reporting licensure annually to the FDA? Yes No

10. Does this facility purchase either from an FDA registered manufacturer and/or from an accredited Drug Distributor that purchased the drug/device directly from the manufacturer? Yes No

***If your facility is not Drug Distributor accredited through NABP**, please review the standards available at the NABP website <https://nabp.pharmacy/> and provide a notarized letter to the Board certifying your facility's compliance with these standards. South Carolina Board of Pharmacy Policy No. 145 requires Non-Resident Wholesale/Distributors to have Drug Distributor accreditation **or** meet the standards established by NABP (National Association of Boards of Pharmacy) for its Drug Distributor accreditation.

Do you distribute controlled substances? Yes No

If yes, contact SCDHEC Bureau of Drug Control via website at:

www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/

LOCATION OF FACILITY/FACILITIES

Customers in South Carolina to which drugs or devices will be shipped (attach additional sheets if necessary).

Facility Name	City	Telephone No.

OWNERSHIP

Sole Proprietorship Name of Business Entity: _____

Name	City, State	Birth Year

General Partnership **LLP** Name of Partnership/LLP: _____

Partner Name	City, State	Birth Year	% of Ownership

Corporation LLC Legal Name of Corporation/LLC: _____

Is this facility publicly traded? Yes No

Name of Parent Company: _____ State of Incorporation: _____

Name of Individual Owners and Principal Officers	Title	City, State	Birth Year	% of Ownership
1.				
2.				
3.				

DISCIPLINARY HISTORY

If you answer “Yes” to any part of this section, provide a detailed explanation on a separate sheet and attach copies of applicable court documentation. Include the city and state where the offense(s) occurred.

TO THE BEST OF YOUR KNOWLEDGE HAS THE APPLICANT, the entity, undersigned permit holder, any person or entity identified in the ownership/management section above, or any entity under common control with the applicant EVER:

- 1. Had any license or permit held by the applicant, permit holder, or by any owner or corporate officer, ever been disciplined, denied, refused, voluntarily surrendered, agreed to permanently cease operations or revoked for violations of any federal or state pharmacy laws or drug laws regardless of state? Yes No
Is there any pending disciplinary action? Yes No
- 2. Been convicted, fined or entered in a plea of guilty or nolo contendere in any criminal prosecution, felony or misdemeanor in South Carolina or any other state, or in a United States court for:
 - a. any offense relating to drugs, narcotics, controlled substances or alcohol, whether or not a sentence was imposed? Yes No
 - b. any offense involving the practice of pharmacy, or relating to acts committed within a pharmacy or drug/device manufacturer setting or incident to pharmacy practice, whether or not a sentence was imposed? Yes No
 - c. any offense involving fraud, dishonesty or moral turpitude whether or not a sentence was imposed? Yes No
- 3. Had an application for a drug/device distributor permit, pharmacy, or pharmacist license, permit or certificate or a technician license or registration, denied, refused in South Carolina or any other state or country? Yes No
- 4. Had disciplinary action taken against you, or a pharmacy or drug manufacturer facility you owned, or a pharmacy or drug/device distributor facility where you were employed, by the Board of Pharmacy (or its equivalent) in South Carolina or any other state or country? Yes No
- 5. Operated, or allowed the facility to operate without a valid permit? Yes No
- 6. Violated the drugs/device laws, rules, statutes and/or regulations of South Carolina, any other state, the United States, or any other country? Yes No

Pursuant to S.C. Code Ann. §40-43-83 (E) The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this jurisdiction and those located outside this State.

ATTESTATION

I declare that I have read and approve the foregoing and the statements are true and correct to the best of my knowledge and belief. I will comply with the requirements contained in the South Carolina Pharmacy Practice Act and I understand I am responsible for any violation(s) occurring during my tenure.

Permit Holder Signature

Date

Print Name of Permit Holder

Title

Permit Holder Email

Phone Number

PRIVACY NOTICE

South Carolina law requires the agency to collect personal information which is only disseminated as required by law. The South Carolina Freedom of Information Act ensures that the public has a right to access appropriate records and information possessed by a government agency. Therefore, some personal information on your renewal application and other documents on file may be subject to public scrutiny or release. The Department collects and disseminates personal information in compliance with The South Carolina Freedom of Information Act, the South Carolina Family Privacy Protection Act and other applicable privacy laws and regulations. Additionally, the Department shares certain information on the application with other governmental agencies for various governmental purposes, including research and statistical purposes.