

South Carolina Department of Labor, Licensing and Regulation **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

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.

All facilities will be inspected before a permit is issued.

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. Items should be provided in the order listed below. Please do not send in binders, folders or use dividers. Ensure all documentation/information is legible and retain copies of all documents for your records.

Pursuant to S.C. Code Ann. 40-43-90(A)(1), application must be received in the Board office at least forty-five (45) days before the required permit is needed to allow for application processing, on-site inspection, and if necessary, written corrective action response.

Using false, fraudulent, forged statement or document, or committing a fraudulent, deceitful or dishonest act or omitting a material fact in obtaining licensure is grounds for discipline or licensure denial.

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

Included N/A

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|------------|---------------|--|
| | | Check or money order only (no cash) in the amount of \$280 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.) |
| | | A letter describing, in detail, the nature of your business |
| | | Include organizational chart from the ultimate parent company down to and including the applicant. |
| | | 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. |
| | | Copies of policies and procedures on security, disaster plans and storage |
| | | Photographs of: |
| | | • Entrance |
| | | o Exit |
| | | • Product area |
| If you are | a <u>virt</u> | ual wholesale/distributor, also include the items below: |
| | | 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 these facilities are in compliance with NABP standards.
 Provide a list of the names and addresses of all contract manufacturers and verification of

FDA registration for each.

Mail application to the address listed at the top of this page.

| | South Ca 110 Cente P.O. Box 1 | artment of Labor, Licensing and Re arolina Board of Pharmacy erview Dr. • Columbia • SC • 29210 .1927 • Columbia • SC 29211-1927 Contact.pharmacy@llr.sc.gov • Fax: 86 llr.sc.gov/bop | 7 | | |
|---|---|---|-------------|-------------|------|
| | WHOLESALE/DIS | TRIBUTOR PERMIT APPLI | CATION | | |
| □ New Facility | | | For Boa | rd Use Only | r |
| | Permit (Permit No.: |) | Date Paid | | |
| □ Change of Na □ Change of Lo | me cation (from one city to | another) | Amount Paid | | |
| □ Change of Ov | | izational chart before and after | Check No. | | |
| change) | | | Inspector | | |
| Type of Activity (cheo □ Wholesale/Di | ek all that apply): stributor | Vholesale/Distributor | | | |
| FACILITY INFORM | ATION | | | | |
| Federal Tax ID No.: | | NABP e-Profile ID No.: | | | |
| Legal Name of Facility | | | | | |
| DBA Name: | | | | | |
| Facility Address: | | | | | |
| City: | | State: | _ Zip: | | |
| Telephone No.: | | Fax No.: | | | |
| County where facility i | s located: | | | | |
| Is application based on | a change in ownership | ? | | □ Yes | 🗆 No |
| If Yes: SC Permit No.: | | | | | |
| Previous Name of Facility | | | | | |
| Name of Designated Representative: Phone No.: | | | | | |
| Email for Designated F | Representative: | | | | |
| Contact Person: | | ding permitting will be sent if other t | - | | |
| | | City: | State: | Zip: | |
| | | p product to? Check all that apply: | | | |
| \Box Pharmacies | \Box Hospitals | | | | |
| Dentists | \square Physicians | 8 | | | |
| • | U Veterinarians | | | | |
| Will the facility utilize a 3PL or separate wholesaler to distribute the product? | | | | □ Yes | 🗆 No |
| If yes, list all name | es and locations of distri | ibutors (attach additional sheets if n | ecessary): | | |
| | | | | _ | |

Type of products distributed. Check all that apply:

| Prescription Drugs | Legend Devices | |
|---------------------------|------------------------------|--|
| \Box Non-Legend Devices | \Box Controlled Substances | |
| Other: | | |

OTC drugs Medical Gases

Do you distribute controlled substances?

 \Box Yes \Box No

If yes, contact SCDHEC Bureau of Drug Control via website at: www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/

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? | \Box 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. | | | | |

Pursuant to SECTION §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.

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. Has 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?

 \Box Yes \Box No

 \Box Yes \Box No

Is there any pending disciplinary action?

| 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 or dishonesty whether or not a sentence was imposed? | □ Yes | 🗆 No |

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.