



## **INSTRUCTIONS – NON-RESIDENT WHOLESALE/DISTRIBUTOR AND/OR MANUFACTURER PERMIT APPLICATION**

This permit authorizes a facility outside the state to engage in the wholesale distribution of prescription drugs and devices to permitted facilities and licensed practitioners inside the state of South Carolina.

The permit holder for the applicant must attend an Application Review Committee meeting at the Board's office. Applicant will be notified by email of the date and time of the meeting for which they are scheduled. **All requested information and emailed confirmation are required prior to the meeting date.** 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.

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.

South Carolina Non-Resident Wholesale/Distributor and/or Manufacturer Permit Application is good for one (1) year from the date of receipt.

### **Include with your application:**

- Check or money order in the amount of \$700.00 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.)
- Copy of recent operational inspection report. Inspection must have been conducted within the last 2 years. You must also supplement your application by providing the Board's staff with an inspection report received between the date of the application and the date of the application review hearing.
- Copy of FDA inspection, and 483(s) issued and company response.
- Copy of current DEA registration.
- Copy of state controlled substance registrations.
- Copy of Drug Distributor certificate or attestation.
- Copy of policy and procedure for monitoring temperature and humidity.
- Copy of policy and procedure for shipping refrigerated products.
- Copy of licensure from resident state.
- Letter describing, in detail, the nature of your business.
- Provide a list of all pharmacy permits/licenses and license numbers held in other states.
- Sample Transaction Information/History/Statement (T3).
- Customer List
- List of Vendors
- Photographs
  - Entrance
  - Exit
  - Product Area
- Include organizational chart. If a change of ownership, include charts of before and after the change. The chart must show the legal business entities from the ultimate parent company down to and including the applicant and must include the legal business name, trade name, and type of ownership for each entity on the chart. Chart must include owner's name with a ten percent or greater ownership interest in a non-publicly traded company.



**NON-RESIDENT WHOLESALE/DISTRIBUTOR AND/OR  
 MANUFACTURER PERMIT APPLICATION**

FOR BOARD USE ONLY	
Date Paid	
Amount Paid	
Check No.	

New Facility

Change to Existing Permit (Permit No.: \_\_\_\_\_)

Check Type of Activity:

Change of Name

Wholesale Distributor

Repackager

Change of Location (From one city to another)

Manufacturer

Broker

Change of Ownership (**include organizational chart before and after change**)

NABP e-Profile ID No.: \_\_\_\_\_

Facility Name: \_\_\_\_\_ FEIN No.: \_\_\_\_\_

Trade Name of Facility (d/b/a) to License: \_\_\_\_\_

Name of Contact Person at this site: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_ Email: \_\_\_\_\_

Mailing Address where all correspondence regarding licensure will be sent if other than facility physical address above:

Contact Person: \_\_\_\_\_ Email: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

1. Has your facility been inspected by the FDA?  YES  NO

2. If inspected by the FDA, was your facility issued a 483?  YES  NO

**If Yes**, provide a copy of the FDA Form 483 and your company's response to the issues noted.

3. Are you currently shipping into South Carolina from this facility?  YES  NO

**If Yes**, provide a list of customers.

4. Do you ship legend products outside the United States?  YES  NO

5. Do you order legend product from the other manufacturers, wholesalers or pharmacies?  YES  NO

**If Yes**, provide a list of company names and addresses.

6. Do you receive or distribute any legend products from outside the United States?  YES  NO

**If Yes**, provide a list of company names and addresses.

7. Which of the following entities do you sell/ship product to? Check all that apply:

Pharmacies

Hospitals

Permitted Clinics/Surgical Centers

Dentists

Physicians

Podiatrists

Nursing Homes

Veterinarians

Optometrists

Other (specify): \_\_\_\_\_

8. Has the facility or have the owners previously applied for a permit in South Carolina?  YES  NO

**If Yes**, state business name on application: \_\_\_\_\_

Month/Year submitted: \_\_\_\_\_

Status of application:  Denied  Withdrawn  Pending  Permit No. Issued: \_\_\_\_\_

9. Does your facility have Drug Distributor Accreditation through NABP?  YES  NO

10. Have you ever applied for Drug Distributor Accreditation?  YES  NO

**If Yes**, what is the status of the application? \_\_\_\_\_

**\*If your facility is not Drug Distributor accredited through NABP**, please review the standards available at the NABP website [www.NABP.pharmacy](http://www.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.

**CONTROLLED SUBSTANCES**

Non-resident wholesalers/distributors/manufacturers permitted by the SC Board of Pharmacy who distribute or manufacture controlled substances are required to obtain a South Carolina Controlled Substances Registration from the SCDHEC-Bureau of Drug Control. Access the application via the website at [www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/](http://www.dhec.sc.gov/Health/FHPF/DrugControlRegisterVerify/NewRegistrations/)

Do you manufacture and/or distribute controlled substances?  YES  NO

**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   Name of Corporation/LLC: \_\_\_\_\_

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 a permit or professional license disciplined, denied, refused or revoked for violations of any federal or state pharmacy laws or drug laws?  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 distributor 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 distributor 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, statues and/or regulations of South Carolina, or any other State or Country or the United States?  YES    NO

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.

**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 for non-resident wholesale distributors/manufacturers as contained in the South Carolina Pharmacy Practice Act and I understand I am responsible for any violation(s) occurring during my tenure.

\_\_\_\_\_  
Signature of Responsible Person Acting as Permit Holder

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Permit Holder Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Email Address of Permit Holder or Contact Person

\_\_\_\_\_  
Phone Number

**Mailing Address:**

South Carolina Board of Pharmacy  
P.O. Box 11927  
Columbia, South Carolina 29211-1927

**Overnight/Physical Address:**

South Carolina Board of Pharmacy  
110 Centerview Drive  
Columbia, South Carolina, 29210