



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

MANUFACTURER/REPACKAGER PERMIT APPLICATION REQUIREMENTS AND INSTRUCTIONS

A Manufacturer/Repackager Permit is required for a facility to engage in the manufacturing of prescription drugs or devices, including any packaging or repackaging of the drugs and/or devices, and/or labeling or re-labeling of containers. A South Carolina Manufacturer/Repackager Permit Application has a one-year expiration.

If you are also distributing your own products, you will need to apply concurrently for a wholesale distributor permit.

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

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 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.) |
| <input type="checkbox"/> | <input type="checkbox"/> | A letter describing, in detail, the nature of your business |
| <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. |
| <input type="checkbox"/> | <input type="checkbox"/> | Copies of policies and procedures on security, disaster plans and storage |
| <input type="checkbox"/> | <input type="checkbox"/> | Photographs of: <ul style="list-style-type: none">○ Entrance○ Exit○ Product area |

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

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 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. |
|--------------------------|--------------------------|--|

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



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MANUFACTURER/REPACKAGER PERMIT APPLICATION

- Form fields for facility type and changes: New Facility, Change to Existing Permit, Change of Name, Change of Location, Change of Ownership.

Table with 2 columns: Label (Date Paid, Amount Paid, Check No., Inspector) and empty space for data.

Type of Activity (check all that apply):

- Form fields for activity type: Labler/Relabler, Manufacturer, Packager/Repackager, Virtual Manufacturer.

FACILITY INFORMATION

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 in which facility is located: _____

Expected Opening Date: _____ Days and Hours Open: _____

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 Representative: _____

Mailing Address where all correspondence regarding permitting will be sent if other than facility above:

Facility Name: _____

Mailing Address: _____ City: _____ State: ___ Zip: _____

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

- Form fields for product recipients: Pharmacies, Hospitals, Clinics/Surgical Centers, Dentists, Physicians, Podiatrists, Nursing Homes, Veterinarians, Optometrists, Other (specify).

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):

Do you manufacture, repackage, relabel or distribute controlled substances? Yes 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? 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?

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 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.