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

NON-RESIDENT OUTSOURCING PERMIT APPLICATION REQUIREMENTS AND INSTRUCTIONS

A Non-Resident Outsourcing Facility permit is required for a facility engaged in the compounding of sterile drugs and has elected to register with the U.S. Food and Drug Administration as a 503(b) outsourcing facility. To obtain a permit as an outsourcing facility, a facility must hold, or concurrently apply for, a non-resident pharmacy or wholesale distributor permit. A South Carolina Non-Resident Outsourcing Facility Permit Application has a one-year expiration.

The permit holder for the outsourcing facility is responsible for the supervision and control of compounded drugs and must be a licensed pharmacist. The pharmacist responsible for compounding must attend an Application Review Committee meeting at the Board's office. Applicant will be notified by mail 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 permit 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. Only use one side of paper. Please write legibly. Retain copies of everything you have provided.**

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.

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

Included	N/A	
☐	☐	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.)
☐	☐	Copy of all operational inspection reports conducted within the last two years
☐	☐	Copy of FDA inspection, any 483(s) issued, and applicant's response
☐	☐	Copy of current DEA registration
☐	☐	Copy of Responsible Pharmacist's license
☐	☐	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
☐	☐	Provide a list of all pharmacists practicing at this facility with documentation of compounding training and last 2 years of continuing education
☐	☐	Photographs of: o Exterior of building o All compounding areas
☐	☐	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.

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

CONTROLLED SUBSTANCE INFORMATION

Non-resident facilities permitted by the SC Board of Pharmacy who distribute controlled substances are required to obtain a South Carolina Controlled Substances Registration from the SCDHEC-Bureau of Drug Control. Access to the application via the website at

https://scdhec.gov/healthcare-quality/drug-control-register-verify/new-registrations

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NON-RESIDENT OUTSOURCING FACILITY PERMIT APPLICATION

☐ New Facility

☐ Change to Existing Permit (Permit No.: _____)

- ☐ Change of Name
- ☐ Change of Location (from one city to another)
- ☐ Change of Ownership (include organizational chart before and after change)

FOR BOARD USE ONLY	
Date Paid	
Amount Paid	
Check No.	

FDA reg. No.:_____ Resident State License No.:_____ FEIN: _____

Legal Facility Name: _____

DBA Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

Is application based on a change in ownership? ☐ Yes ☐ No

If Yes: _____ SC Permit No.: _____
Previous Owners/Name of Pharmacy

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: _____

Address: _____ City: _____ State: ____ Zip: _____

TYPE OF COMPOUNDING ACTIVITY

1. Does the outsourcing facility engage in CATEGORY 3 compounding of sterile drug products? ☐ Yes ☐ No
2. Does the outsourcing facility engage in CATEGORY 2 compounding of sterile drug products? ☐ Yes ☐ No
3. Does the outsourcing facility engage in CATEGORY 1 compounding of sterile drug products? ☐ Yes ☐ No
4. Does the outsourcing facility engage in the compounding of NON-STERILE drug products? ☐ Yes ☐ No
5. Does the outsourcing facility dispense compounded drugs pursuant to valid prescriptions? ☐ Yes ☐ No
   ***If Yes,** a pharmacy permit is required. Outsourcing facilities which share the same space with a pharmacy must perform all compounding in compliance with cGMPs.
6. Do you compound and/or distribute controlled substances? ☐ Yes ☐ No
7. Has your facility been inspected by the FDA? ☐ Yes ☐ No

8. If inspected by the FDA, was your facility issued any 483? ☐ Yes ☐ No
   If Yes, attach a copy of the FDA Form 483 and your company's response to the issue noted. ☐ Yes ☐ No
9. Are you currently shipping into South Carolina from this facility? ☐ Yes ☐ No
   If Yes, attach a list of customers.
10. Provide licensure information for the pharmacist responsible for oversee compounding at the facility:

    Name: _____ License No.: _____ Expiration Date: _____
11. Which of the following entities do you sell/ship product to? Check all that apply:

    ☐ Retail Pharmacies ☐ Hospital Pharmacies ☐ Clinics/Surgical Centers

    ☐ Practitioners (MD, DMD, DVM, APRN, PA-C) ☐ Other (specify): _____

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. 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, dishonesty 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 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 contained in the South Carolina Pharmacy Practice Act and I understand I am responsible for any violation(s) occurring during my tenure.

Signature of Permit Holder	Date
Print Name of Permit Holder	Title
Email Address of Permit Holder	Phone Number

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.

Signature of Pharmacist Responsible for Compounding	Date
Print Name of Pharmacist Responsible for Compounding	Title
Email Address of Pharmacist Responsible for Compounding	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.