South Carolina Department of Labor, Licensing and Regulation
South Carolina Board of Pharmacy
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2025-2026 NON-RESIDENT OUTSOURCING 503B PERMIT RENEWAL

Renewal Requirements and Instructions

FOR BOARD USE ONLY	
Date Paid	
Check No.	
Amount Paid	

- Submit this permit renewal directly to the Board by going to: https://eservice.llr.sc.gov/DocumentSubmission/. You will pay the renewal fee through this document submission process via debit/credit card or electronic check.

  Note: If mailing the paper application, submit the renewal fee in the form of a check or money order (no cash) payable to SC Board of Pharmacy. (All fees are non-refundable. A returned check fee of up to $30, or an amount specified by law, may be assessed on all returned funds.)
- **Attach a copy of the most recent facility inspection report (FDA or state).**
- **Renewal / Late Fees:**
  Postmarked before 6/1/2025: **$700**
  Postmarked on or after 6/1/2025: Late Fee $50 + Renewal Fee $700 = **$750**
- Beginning July 1, 2025, lapsed permits will be assessed fees of $10/day until the permit is reinstated.
- Permits not renewed by June 30, 2025, are lapsed and may not operate. A facility that operates with a lapsed permit is in violation of S.C. Code Ann. § 40-43-140 and may be subject to disciplinary action. A permit holder who allows a site to operate with a lapsed permit is in violation of S.C. Code Ann. § 40-43-83 and may be subject to disciplinary action.
- If there has been a change in ownership, legal name change, change in business form, or relocation of the facility, contact the Board before renewing the permit.

FACILITY INFORMATION

Federal Tax ID No.: _____ SC Permit No.: _____

SC DPH Controlled Substances Registration No. (if applicable): _____

DEA Registration No. (if applicable): _____ Expiration Date: _____

Resident State License No.: _____ Expiration Date: _____

NABP e-Profile ID (if applicable): _____

Legal Name of Facility: _____

DBA Name: _____

Facility Address (physical): _____

Email: _____ Phone: _____

Permit Holder Name: _____ Phone: _____

Email: _____

Pharmacist responsible for overseeing compounding at this facility:

Name: _____ License No.: _____

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

Facility Name: _____

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

FACILITY OPERATIONS

Days and Hours of Operation: _____

1. Does this facility distribute, store, or manufacture controlled substances? ☐ Yes ☐ No
2. Has there been a change in ownership, legal name change, change in business form, or relocation of the facility?
   ☐ Yes – Contact the Board of Pharmacy office before completing this application. ☐ No
3. Is this facility compliant with the Drug Supply Chain Security Act (DSCSA)? ☐ Yes ☐ No
   Access information on DSCSA at www.llr.sc.gov/bop.
4. Which of the following entities do you sell/ship products to? (Check all that apply)
   ☐ Retail Pharmacies ☐ Hospital Pharmacies ☐ Permitted Clinics/Surgery Centers
   ☐ Practitioners (MD, DMD, DVM, APRN, PA-C) ☐ Other: _____

COMPOUNDING

1. Does this facility engage in category 3 compounding of sterile drug products? ☐ Yes ☐ No
2. Does this facility engage in category 2 compounding of sterile drug products? ☐ Yes ☐ No
3. Does this facility engage in category 1 compounding of sterile drug products? ☐ Yes ☐ No
4. Does this facility engage in the compounding of non-sterile drug products? ☐ Yes ☐ No
5. Does this facility compound hazardous medication? ☐ Yes ☐ No
6. Does this facility dispense compounded drugs pursuant to valid prescriptions? ☐ Yes ☐ No
   If yes, a pharmacy permit is required. Outsourcing facilities which share the same space as a pharmacy must perform all compounding in compliance with cGMPs.
   Pharmacy Permit No., if applicable: _____
7. Has this facility been inspected by the FDA? ☐ Yes ☐ No
   If yes, was the facility issued a 483? ☐ Yes ☐ No
   If yes, provide a copy of the FDA form 483 and the company's response to the issues noted.
8. Have all personnel involved in compounding completed annual continuing education and/or training in the last year? ☐ Yes ☐ No

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, SINCE THE LAST RENEWAL has the applicant, the business entity, undersigned permit holder, pharmacist responsible for compounding, any person or entity identified as holding a position in ownership/management, or any entity under common control with the applicant:

1. Had any license or permit held by the applicant, permit holder, pharmacist responsible for compounding, or by any owner or corporate officer, 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

a. 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? ☐ Yes ☐ No

   a. Is there any legal action pending related to violations of any federal or state pharmacy laws or drug laws regardless of the jurisdiction of legal action? ☐ 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 by any professional licensing board in South Carolina or any other state or country against the applicant, permit holder, pharmacist responsible for compounding, or by any owner or corporate officer? ☐ Yes ☐ No

5. Had disciplinary action taken by the Board of Pharmacy (or its equivalent) in South Carolina or any other state or country against a pharmacy or drug/device manufacturer facility owned by the applicant, permit holder, pharmacist responsible for compounding, or by any owner or corporate officer or against a pharmacy or drug/device manufacturer facility at which the applicant, permit holder, pharmacist responsible for compounding, or any owner or corporate officer was employed? ☐ Yes ☐ No

6. Operated, or allowed any facility to operate, without a valid permit? ☐ Yes ☐ No

7. 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

PERMIT HOLDER 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 all federal and state laws related to operations at the above-named facility, and I understand I am responsible for any violation(s) of law occurring during my tenure.

I understand that 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.

_____ _____

Permit Holder Signature Date

PHARMACIST RESPONSIBLE FOR COMPOUNDING ATTESTATION

I hereby certify that the facility for which this permit renewal is sought will be conducted in full compliance with federal and South Carolina law pertaining to its pharmaceutical operations, and that the facility shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs. I understand that I am responsible for abiding by the statutes and regulations governing my role as the facility's pharmacist responsible for compounding. I certify that I have read and approved the foregoing and the statements are true and correct to the best of my knowledge and belief.

_____ _____

Pharmacist Responsible for Compounding Signature Date