South Carolina Department of Labor, Licensing and Regulation
South Carolina Board of Pharmacy
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2023-2024 RENEWAL OUTSOURCING FACILITY (503B) PERMIT

FOR BOARD USE ONLY	
Check No.	
Amount Paid	
Date Processed	
Returned Incomplete	

Renewal Instructions:

- 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.

Renewal Requirements:

- If mailing paper application: 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.)
- **Renewal / Late Fees:**
  Postmarked before 6/1/2023: **$140**
  Postmarked on or after 6/1/2023: Late Fee $50 + Renewal Fee $140 = **$190**
- Beginning July 1, 2023, lapsed permits will be assessed fees of $10/day until the permit is reinstated.
- Submit a copy of the facility's most recent inspection report via document submission.
- Permits not renewed by June 30, 2023, 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 result in 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 result in disciplinary action.
- If there has been a 50% or more change in ownership, contact the Board before renewing the permit.

FACILITY INFORMATION

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

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

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

Facility Name: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Phone No.: _____ Hours of Operation (ex. 9AM–9PM): _____

Contact Person: _____ Email: _____

Fax No.: _____

Has there been a change in ownership of 50% or more since last renewal that has not been reported to the Board?
☐ Yes – Contact the Board of Pharmacy office before completing this application. ☐ No

1. Does the facility engage in HIGH-RISK compounding of sterile drug products? ☐ Yes ☐ No
2. Does the facility engage in MEDIUM-RISK compounding of sterile drug products? ☐ Yes ☐ No
3. Does the facility engage in LOW-RISK compounding of sterile drug products? ☐ Yes ☐ No
4. Does the facility engage in the compounding of NON-STERILE drug products? ☐ Yes ☐ No
5. Do you compound hazardous medication? ☐ Yes ☐ No
6. Does the 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.

7. Has the facility been inspected by the FDA? Date: _____ ☐ Yes ☐ No

8. If inspected by the FDA, was the 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.

9. Does your facility distribute, store or manufacture controlled substances? ☐ Yes ☐ No

9a. 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: _____

10. Does the facility hold pharmaceutical licenses or permits in any other states? ☐ Yes ☐ No
    If Yes, provide the state, license number and type. Attach additional sheet if necessary.

    State: _____ License No.: _____ Type: _____

    State: _____ License No.: _____ Type: _____

    State: _____ License No.: _____ Type: _____

    State: _____ License No.: _____ Type: _____

11. Have any out-of-state licenses or permits been restricted, revoked, suspended or otherwise disciplined? **If Yes,** provide a copy of the disciplinary action. ☐ Yes ☐ No

NAME OF PHARMACIST RESPONSIBLE FOR OVERSEEING COMPOUNDING AT THIS FACILITY:

Name: _____ License No.: _____

ATTESTATION

I hereby certify that the facility, for which this permit renewal is sought, will be conducted pursuant to federal and South Carolina law pertaining to its pharmaceutical operations, and that the facility will be under the supervision of a Consultant Pharmacist as required by the South Carolina Pharmacy Practice Act and Regulations promulgated thereunder. I understand that the location for which this permit is issued is subject to inspection by the Board of Pharmacy. I understand that I am responsible for abiding by the statutes and regulations governing my role as the facility's permit holder.

_____ _____
Permit Holder Signature Date

_____ _____
Print Name of Permit Holder Title

Permit Holder Email: _____

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.