



2020-2021 RENEWAL 503B OUTSOURCING FACILITY PERMIT

Renewal Instructions/Requirements:

- 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.)
- **Fee:** Postmarked before **September 30, 2020: \$140**
Postmarked on/after **October 1, 2020: \$190**
- Permits not renewed by **September 30, 2020**, are lapsed and may incur disciplinary action by the Board.
- On October 1, lapsed permits will be assessed fees of \$10/day until the permit is reinstated
- A completed application must be postmarked before September 30, 2020.
- Information from this renewal may be shared.

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

Permit No.: _____ Federal tax ID No.: _____

Facility Name: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Hours of Operation (ex. 9AM–9PM): _____

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 NUMBER: _____

ATTESTATION

I hereby certify that the facility, for which this permit renewal is sought, will be conducted with federal and South Carolina law pertaining to its pharmaceutical operations, and that the facility will be under the supervision of a Responsible 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.

Permit Holder Signature _____
Date

Print Name of Permit Holder _____
Title

Permit Holder Email: _____

I hereby certify that as Responsible Pharmacist, I will be responsible for all duties connected with the proper and lawful conduct of this facility, as required by the South Carolina Pharmacy Practice Act.

Responsible Pharmacist Signature _____
Date

Print Name of Responsible Pharmacist

Responsible Pharmacist Email: _____

Mail completed application with self-inspection report to:

SCBOP, 110 Centerview Drive, Columbia, SC 29210

Permits not renewed by September 30, are lapsed and will be assessed ten dollars (\$10) a day until the permit is reinstated, plus the fifty-dollar (\$50) penalty fee, and the renewal fee (\$140). A permit holder who allows a site to operate with a lapsed permit is in violation of Section 40-43-83.

A permit holder who allows a site to operate with a lapsed permit is in violation of Section 40-43-83 and disciplinary action may result.