



## 2021-2022 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.)
- **Renewal / Late Fees:**  
 Postmarked before 6/1/2021: **\$140**  
 Postmarked on or after 6/1/2021: Late Fee \$50 + Renewal Fee \$140 = **\$190**
- Beginning July 1, 2021, lapsed permits will be assessed fees of \$10/day until the permit is reinstated.
- Attach copy of most recent self-inspection report.
- Permits not renewed by June 30, 2021, are lapsed and may not operate. A permit holder who allows a site to operate with a lapsed permit is in violation of Section 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.
- Information from this renewal may be shared.

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

### FACILITY INFORMATION

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

- Does the facility engage in HIGH-RISK compounding of sterile drug products?  Yes  No
- Does the facility engage in MEDIUM-RISK compounding of sterile drug products?  Yes  No
- Does the facility engage in LOW-RISK compounding of sterile drug products?  Yes  No
- Does the facility engage in the compounding of NON-STERILE drug products?  Yes  No
- Do you compound hazardous medication?  Yes  No
- 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.
- Has the facility been inspected by the FDA? Date: \_\_\_\_\_  Yes  No
- 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.
- 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: \_\_\_\_\_

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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 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: \_\_\_\_\_

**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.