

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

# 2021-2022 RENEWAL NON-RESIDENT 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: \$700 Postmarked on or after 6/1/2021: Late Fee \$50 + Renewal Fee \$700 = \$750
- FOR BOARD USE ONLY

   Check No.

   Amount Paid

   Date Processed

   Returned Incomplete
- Beginning July 1, 2021, lapsed permits will be assessed fees of \$10/day until the permit is reinstated.
- Attach copy of most recent inspection report (FDA or state).
- 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.

### FACILITY INFORMATION

Permit No.:	Federal Tax ID No.:			
Resident State License No.:	Expiration D	Date:		
SC DHEC Control Substance Registration No:				
DEA Registration No.:	Expiration D	ate:		
Facility Name:				
Facility Address:				
City:	State:	Zip:		
Phone No.:	Fax No.:			
Contact Person:	Email:			
Mailing address where all correspondence regarding	licensure will be mailed	, if other th	an facility a	ibove:
Facility Name:				
Facility Address:	City:	_State:	_Zip:	
Has there been a change in ownership of 50% or more si $\Box$ Yes – Contact the Board of Pharmacy office before co		-	ported to the	Board?
1. Have any out-of-state licenses or permits been re otherwise disciplined? <b>If Yes,</b> provide a copy of	, i i	ded or	□ Yes	🗆 No
2. Does the facility engage in the compounding of I	NON-STERILE drug pro	ducts?	□ Yes	🗆 No
3. Do you compound hazardous medication?			□ Yes	🗆 No
4. Does the facility dispense compounded drugs pu	rsuant to valid prescription	ons?	□ Yes	🗆 No
5. Has the facility been inspected by the FDA? Dat	e:		□ Yes	🗆 No

2021-2022 Non-Resident 503B Outsourcing Facility Permit Renewal (3/21)

6.	. If inspected by the FDA, was the facility issued a 483?			
	If Yes, provide a copy of the FDA Form 483 and your company's response to the issues noted.			

7. Does your facility distribute, store or manufacture controlled substances?

8.	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:		

#### ATTESTATION

I hereby certify that the facility for which this permit renewal is sought, will be conducted in full compliance 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 I am responsible for any violations during my tenure.

Permit Holder Signature	Date	
Print Name of Permit Holder	-	
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 federal law and the South Carolina Pharmacy Practice Act and for overseeing compounding at this facility.

**Responsible Pharmacist Signature** 

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.

 $\Box$  Yes  $\Box$  No

 $\Box$  Yes  $\Box$  No

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Date

Date