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
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NON-RESIDENT CONTRACT MANUFACTURER/REPACKAGER PERMIT APPLICATION REQUIREMENTS AND INSTRUCTIONS

A separate Non-Resident Manufacturer/Repackager permit is required for each of the following entity types pursuant to SC Code Reg. Section 99-43(H):

- manufacturer, which includes packaging/repackaging and labeling/relabeling,
- virtual manufacturer, and
- contract manufacturer.

A Non-Resident Contract Manufacturer/Repackager Permit is required for an entity that manufactures a finished drug or device to another entity's specifications. This includes:

- any packaging or repackaging of the drugs and/or devices, and/or
- labeling or re-labeling of containers that will be distributed into South Carolina.

Virtual Manufacturers are defined as any company that sells their own prescription drug products and/or medical devices but outsources the manufacturing and distribution operations.

A separate wholesale distributor permit is required for distribution of the manufactured drugs and/or legend devices.

Any Third-Party Logistics Provider (3PL) and/or a wholesale distributor used to distribute the manufactured products into South Carolina must be appropriately permitted in South Carolina.

Regulations Section 99-43 requires a separate permit for each business practice in which a facility engages.

A South Carolina Permit application expires one year after submission to the Board. After one year, a new application, supporting documentation, and fees, must be submitted. If your permit application is approved **before** **April 1st**, you must renew your permit before **June 1st** to avoid a late fee.

REQUIRED CONTACT(S)

A **permit holder** is an individual who is responsible for and accountable for ensuring compliance with all federal and State law related to the facility. This individual is responsible for any violation(s) of law occurring in relation to the facility as well as ensuring the information related to this application and all permit renewal applications are true and accurate.

A **designated representative** is an individual who is responsible and accountable for and actively involved in and aware of the performance and operation of the facility or entity, its personnel and as required by law, all other entities or individuals providing services related to daily operations. This individual may also be responsible for any violation(s) of law related to the handling and/or distribution of drugs and/or medical devices at or from the permitted facility or entity. An individual may only be designated representative for one permitted facility/location.

The designated representative or other individual knowledgeable about the applicant's operations may be requested to attend an application review meeting to answer questions regarding the applicant's operations.

CHANGE TO AN EXISTING PERMIT

A new application should be submitted for permitted facilities that meet the requirements for any of the changes listed below. The facility may continue to operate under the facility's existing permit until the new permit is issued. Detailed information on making changes to an existing permit is located on the Frequently Asked Questions page under "Facilities" on the Board website.

Change of Ownership: A new application must be submitted to the Board when there is a change of 50% or more in ownership at the permitted entity parent level. The application should be submitted within 30 days post-change of ownership with organizational charts of before and after the change. The chart must show the legal business entities from the ultimate parent company down to and including the applicant and must include the legal business name, trade name, and type of ownership for each entity on the chart. The chart must include the names of owners with a ten percent (10%) or greater ownership interest in a non-publicly traded company. Do not send personnel organizational charts showing roles of personnel employed by the company.

Change of Legal Name: A new application must be submitted when there is a change in the legal name (not DBA name). The application should be submitted within 30 days post-name change.

Change of Location (to another city): A new application must be submitted within 30 days of post-facility relocation.

CONTROLLED SUBSTANCE PROVIDER

Non-Resident Contract Manufacturers/Repackagers permitted by the SC Board of Pharmacy who manufacture or repackage controlled substances are required to obtain a South Carolina Controlled Substances Registration from the SCDPH-Bureau of Drug Control. Access the application via the website at https://dph.sc.gov/professionals/healthcare-quality/drug-control-register-verify/new-registrations.

Using false, fraudulent, forged statement or document, or committing a fraudulent, deceitful or dishonest act or omitting a material fact in obtaining licensure is grounds for discipline or licensure denial.

Failure to complete all required fields and/or provide necessary supplemental documentation will delay the application process. **In order to avoid delay, please do not provide the items below in a binder, folder or use dividers.**

Provide items in the order listed below and retain copies of all documents for your records.
An application is not complete until receipt of the required items below.

Required items:

- ☐ Check or money order only (no cash) in the amount of $700 made payable to SC Board of Pharmacy. (Application fee is non-refundable. A returned check fee of up to $30, or an amount specified by law, may be assessed on all returned funds.)
- ☐ Letter describing, in detail, the nature of your business
- ☐ Photographs of:
  - Entrance including company signage
  - Product storage area
  - Product manufacturing area
  - Quarantine area
  - Controlled substance safe, cage, or vault (if applicable)
  - Work Area/office space
  - Exit

☐ Copy of policy and procedures for the following:
- Security
- Disaster plans
- Storage
- Recordkeeping
- Shipping refrigerated products
- Monitoring temperature and humidity

☐ Copy of all operational inspection reports conducted within the last two years

☐ Copy of license/permit from resident state

☐ Copy of FDA registration

☐ List of all virtual manufacturers for which this facility manufactures products, including the name, address, and South Carolina permit number for each. Include a copy of the virtual manufacturer's resident state permit.

☐ Organizational chart from the ultimate parent company down to and including the applicant

☐ List of products manufactured for each virtual manufacturer

☐ List of all 3PLs or wholesalers utilized, including the name, address, and South Carolina permit number for each. If available, provide the Drug Distributor accreditation certificate or a notarized letter certifying these facilities are in compliance with NABP standards.

Other documentation, check N/A if not applicable. Please include this checklist with the completed application.

Included	N/A	
☐	☐	If application is due to a change of ownership, include organization charts of before and after the change. The chart must include names of owners with a 10% or greater ownership interest if they are a non-publicly traded company.
☐	☐	Copy of FDA inspection, any 483 issued, and applicant's response (all unredacted)
☐	☐	Copy of current DEA registration
☐	☐	Copy of controlled substance registration issued by resident state
☐	☐	List of all pharmacy permits/licenses, license types and license numbers held in other states
☐	☐	List of all drug recalls within the past 2 years including the product recalled and the reason for the recall

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NON-RESIDENT CONTRACT MANUFACTURER/REPACKAGER PERMIT APPLICATION

This is a fillable form. Please download and save before completing.

☐ New Facility ($700)

☐ Change to an Existing Permit ($700)
Permit No.: _____
- ☐ Change of legal name
- ☐ Change of location (from one city to another)
- ☐ Change of ownership (include organizational charts of before and after change)

For Board Use Only	
Date Paid	
Amount Paid	
Check No.	

FACILITY INFORMATION

Federal Tax ID No.: _____ NABP e-Profile ID No.: _____

Legal Name of Facility: _____

DBA name: _____

Facility Address: _____

City: _____ State: _____ Zip: _____ Telephone: _____

Mailing address where all correspondence regarding licensure will be mailed if other than facility above:

Mailing Address: _____

Days and Hours of Operation: _____

OWNERSHIP

Business Type: ☐ Sole Proprietorship ☐ Partnership ☐ Corporation ☐ Other (Specify): _____

Is this facility/company publicly traded? ☐ Yes ☐ No

Name of Parent Company: _____ State of Incorporation: _____

List the names of owners with 10% or greater ownership. This is not required for publicly traded companies.

Name of Individual Owners, Partners or Principal Officers	Title	% of Ownership
1.		
2.		
3.		

PERMIT HOLDER

A permit holder is the individual who is responsible for and accountable for ensuring compliance with all federal and State law related to the facility. This individual is responsible for any violation(s) of law occurring in relation to the facility as well as ensuring the information related to this application and all permit renewal applications are true and accurate.

Name of Permit Holder: _____

Email for Permit Holder: _____ Phone: _____

(Must be a direct email address for the permit holder. Staff will contact the permit holder directly with questions related to the application or permit.)

DESIGNATED REPRESENTATIVE

The Designated Representative is the individual who is responsible and accountable for and actively involved in and aware of the performance and operation of the facility or entity, its personnel, and as required by law, all other entities or individuals providing services related to daily operations. This individual may also be responsible for any violation(s) of law related to the handling and/or distribution of drugs and/or medical devices at or from the permitted facility or entity.

Name of Designated Representative: _____

Email for Designated Representative: _____ Phone: _____

(Must be a direct email address for the designated representative. Staff will contact the designated representative directly with questions related to the application or permit.)

LICENSES

1. Are you permitted in any state other than your resident state? ☐ Yes ☐ No
   If yes, provide a list of all pharmacy permits and/or licenses, license types, and license numbers held in other states.

DISTRIBUTORS

1. Will the facility utilize a 3PL or wholesaler to distribute the product? ☐ Yes ☐ No

   If yes, submit a list of 3PL and/or wholesalers to be used, including name, address, and South Carolina permit numbers.

2. Are your products currently being distributed into South Carolina? ☐ Yes ☐ No

CONTROLLED SUBSTANCES

1. Will this facility manufacture, repackage, relabel or distribute controlled substances? ☐ Yes ☐ No

   If the facility manufactures distributes controlled substances and the resident state requires a state-level controlled substance registration, a copy of both the DEA and state-level registration needs to be included with the application.

FDA

1. Has the facility been inspected by the FDA? ☐ Yes ☐ No
2. If inspected by the FDA, was the facility issued a 483? ☐ Yes ☐ No
   If yes, provide a copy of the FDA Form 483 and the facility's response to the issues noted.
3. Is this facility reporting licensure information annually to the FDA? ☐ Yes ☐ No

RECALLS

1. Have you recalled any drugs within the past two years? ☐ Yes ☐ No
   If yes, provide a list of all drug products recalled and the reason for each recall.

DISCIPLINARY HISTORY

For any "Yes" answers below, please provide and submit a detailed explanation for each person or entity to whom a Yes answer applies. Official documentation of judgment(s) or disposition(s) must also be provided by the applicable person and/or the entity's authorized agent, as well as the city and state where the offense(s) or discipline occurred.

To the best of your knowledge, has the applicant, the entity, undersigned permit holder, designated representative, any person or entity identified as holding a position in ownership/management, or any entity under common control of the applicant:

1. Had a professional license or permit disciplined, denied, refused, voluntarily surrendered, agreed to permanently cease operations, or revoked? ☐ Yes ☐ No
   a. Have any pending disciplinary action or currently under investigation? ☐ Yes ☐ No
2. Been convicted, fined, or entered in a plea of guilty or nolo contendere to a crime (other than a minor traffic offense)? ☐ Yes ☐ No
   a. Have any legal action pending or currently under investigation related to violations of any federal or state pharmacy laws or drug laws regardless of the jurisdiction of legal action? ☐ Yes ☐ No
3. Operated, or allowed any facility to operate, without a valid permit? ☐ Yes ☐ No

PERMIT HOLDER ATTESTATION

☐ I hereby affirm that I have read and approved the forgoing application. I affirm that all information and statements contained herein are true and accurate to the best of my knowledge and belief.

☐ Should additional explanation and/or documentation be required, I accept responsibility to ensure additional explanation and documentation will be provided, if necessary. I further understand that this application will not be processed until all documentation is received.

☐ 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

DESIGNATED REPRESENTATIVE ATTESTATION

☐ I hereby affirm that I have read and approved the foregoing application. I affirm that all information and statements contained herein are true and accurate, to the best of my knowledge and belief.

☐ I understand that I am responsible for abiding by the statutes and regulations governing my role as the facility's designated representative.

☐ I hereby certify that the facility for which this permit is sought will be operated in full compliance with all applicable federal and South Carolina laws.

☐ 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.

_____ _____

Designated Representative Signature Date

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.