



**NORTH CAROLINA DEPARTMENT OF AGRICULTURE
AND CONSUMER SERVICES
FOOD AND DRUG PROTECTION DIVISION
2018**

Steve Troxler, Commissioner
Anita MacMullan, Director
Jeremy Evans, Drug Administrator

STATE USE ONLY

Check./M.O.# _____
Received _____
Amount _____
License No. _____

**PURPOSE OF APPLICATION:
LICENSE TYPE / APPLICATION FEE:**

- Manufacturer \$1000
- Virtual Manufacturer \$1000
- Re-packager \$1000
- Outsourcing Facility (Sterile 503B) \$1000
- Distributor (in-state) \$ 700
- Wholesaler (out-of-state) \$ 700
- Reverse Distributor Only \$ 700
- Pseudoephedrine Only \$ 700
- Third Party Logistic Provider Only \$ 700
- Medical Gases Manufacturer \$1000
- Medical Gas Distributor (in-state) \$ 700
- Medical Gas Supplier (out-of-state) \$ 700

PURPOSE OF APPLICATION

- New Registration
- Renewal
- Change of Ownership
- Change In Location
- Change In Facility Name

Previous Name: _____

If you plan to compound and/or distribute Controlled Substances in North Carolina, this is another division and license. Please Contact Cheanette.Hill@dhhs.nc.gov or 919-733-1765.

Type or print answers to all questions. Use "Not Applicable" where appropriate. **If more space is required, attach supplemental sheets(s) identifying each item corresponding to the license application. Pay non-refundable fee by check or money order payable to "North Carolina Department of Agriculture & Consumer Services." DO NOT SEND CASH.**

Location of Facility:

IN NORTH CAROLINA OUTSIDE NORTH CAROLINA **CURRENT NC LICENSE NUMBER** _____
(Out-Of-State - Attach on-line verification)

Type of Ownership: Individual Partnership Corporation LLC State of Inc. _____

Affiliation:

Name or title under which business is conducted _____
(Please list legal name and d.b.a. name if applicable)

Physical Address: _____
(P.O. Box not acceptable) Number and Street City/State Zip

Mailing Address (if different): _____

Telephone Number _____ Fax Number: _____

E-Mail contact _____

***Renewal notification in October based on e-mail address submitted on application; please notify us if this changes**

Names of officers/partners/managers:

(President's Name)

(Address)

(Vice President's Name)

(Address)

(Secretary/Treasurer's Name)

(Address)

Type or print answers to all questions. Use "Not Applicable" where appropriate. **If more space is required, attach supplemental sheets(s) identifying each item corresponding to the license application.**

Facility Information, if applicable. Please include name and address of all domestic and foreign facility affiliates, the name, phone number, and e-mail address for a responsible point of contact for each affiliate

Name:

Address:

Phone number:

E-mail address:

Has drug registration or license under any local, state, or federal law ever been suspended or revoked?

() Yes () No (If yes, please attach an explanation and certified copies of all documents and records.)

Have you ever been denied issuance of, or pursuant to disciplinary proceedings, refused renewal of a license by any board or agency in North Carolina or any other state?

() Yes () No (If yes, please attach an explanation and certified copies of all documents and records.)

Have any of the owners, partners of the firm, or officers of the corporation ever been convicted of any crime under the laws of the United States, North Carolina, or any other state pertaining to the manufacturing, distribution, sale or dispensing of drugs or narcotics?

() Yes () No (If yes, please attach an explanation and certified copies of all documents and records.)

What education, training, experience, or combination of these are required of employees to assure assigned functions are performed in a manner that ensures that prescription drug quality, safety, and security will be maintained at all times as required by law?

Outsourcing Facility only (below)

Each outsourcing facility at a separate geographic location or address must register separately.

Address	Telephone	Contact Person
_____	_____	_____
_____	_____	_____
_____	_____	_____

Indicate whether the facility intends to compound products on FDA’s drug shortage Yes ___ No ___
For drugs compounded by registered outsourcing facilities that are on the FDA Shortage List, the drug must be compounded after the drug is placed on the drug shortage list and may not be dispensed or administered to a patient after it has been removed from the drug shortage list.

Indicate whether the facility compounds from bulk drug substances Yes ___ No ___
If any ingredients are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of paragraph (3) of 353b, if any.

Licensed/registered in home state(attach copy of home state license & on-line verification or affidavit for out-of-state)Yes ___ No ___

Name and appropriate license/registration number of the pharmacist(s) in direct supervision of drug compounding operation. _____

Proof of valid license/registration to operate as a pharmacy, if applicable. _____

Attach copy of most recent inspection report by appropriate regulatory agency (federal or state) including any findings, observations, and/or corrective actions.

Attach copies of Form FDA483 or warning letter issued relative to inspection, if applicable; include corrective actions provided in response.

FURTHER REQUIREMENTS FOR THE FOLLOWING:

1. **MANUFACTURER / VIRTUAL MANUFACTURER / REPACKAGER / OUTSOURCING FACILITY:**
Must be registered with the FDA and / or have an approved labeler code(s) for the Product (s) with the FDA.

FEI # _____ DUNS # _____ UFI # _____
NDC# _____ NDA# _____ ANDA# _____

2. **PROOF OF REGISTRATION WITH THE FDA (Attach a copy).**

3. **DISTRIBUTOR / REVERSE DISTRIBUTOR / WHOLESALER / THIRD PARTY LOGISTIC PROVIDER / PSEUDOEPHEDRINE ONLY:**

Complete below for **New** applications; Federal Background Checks **Must Be Less Than Two Years Old**

- A. Attach a **Copy Of A Valid, Signed Driver License Of The Applicant** To This Application.
- B. Submit a completed Federal Background Check (instructions listed below) for **each** facility manager and designated representative. No application will be accepted without these documents.

FEDERAL BACKGROUND CHECK PROCEDURE

- Go To Local Law Enforcement / Sheriff' Office
- Request a Finger Print Card and Finger Printing (fee)
- Obtain A Money Order Written To: Treasurer Of The United States
- Submit: Finger Print Card
Money order (Call FBI 304-625-5590 for fee & FBI form OMB-1110-0052)
Cover letter / Full Name
Current Address
Phone Number
Reason for Request (licensing requirement)
- **Place information in envelope and mail to the following address**

FBI Record Request
1000 Custer Hollow Road
Clarksburg, West Virginia 26306

- In 10-12 weeks, you should have the report returned to you from the FBI
- Submit the report along with the completed license application to our department
- No license will be granted until all of this information is collected and reviewed.

I, the undersigned, do hereby certify that all the information contained in this application is complete, true, and correct. In addition, I agree that the business will be operated in compliance with all applicable Federal and State laws and regulations.

Date _____

Applicant Name _____

Owner, Partner, or Officer of Corporation

Title _____

Applicant Signature _____

License expires December 31st of each year

Changes in information supplied in this application must be submitted within 90 days.

Regular Mail:

NCDA & CS
Food & Drug Protection Division
1070 Mail Service Center
Raleigh, N.C. 27699-1070
Telephone: 919-733-7366
Fax: 919-733-6801
Email: Jeremy.Evans@ncagr.gov
Shannon.Redd@ncagr.gov

Overnight Mail (FedEx or UPS):

NCDA & CS
Food & Drug Protection Division
4000 Reedy Creek Road
Raleigh, N.C. 27607
Attn: Shannon Redd

Drug Laws & Regulations:

www.ncagr.gov