



**NORTH CAROLINA DEPARTMENT OF AGRICULTURE
AND CONSUMER SERVICES
FOOD AND DRUG PROTECTION DIVISION
2020**

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

FEIN/Tax ID #: _____

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 & online 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:

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 # _____
LABELER/NDC# _____ NDA# _____ ANDA# _____

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

DISTRIBUTOR / REVERSE DISTRIBUTOR / WHOLESALER / THIRD PARTY LOGISTIC PROVIDER / PSEUDOEPHEDRINE ONLY:

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

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

FEDERAL BACKGROUND CHECK PROCEDURE

Go to the www.fbi.gov/checks website, complete the Available Now: EDO process (the blue box) by first going to Option 1 HOW TO SUBMIT YOUR REQUEST ELECTRONICALLY – click on that link.

When you click on the link, a new page will open. When the page opens, it will say enter your email in the blue box. When you do that, we will send you an email with a PIN number on it – please write this down.

Then, you will click on the part that says “click here”. This will take you to start the paperwork online – your registration. Fill out step by step. At the end, we will send you an email.

You will print the email and mail it to FBI CJIS Division – Summary Request, 1000 Custer Hollow Road, Clarksburg, WV 26306 unless otherwise noted **with your fingerprint card. I would pay the post office to put tracking on your envelope.** After we receive it, it will take approximately 7 business days to send it to you via email. If you would also like the hard copy response, please check the "preferences box" on the application to state that you would like the hard copy response in the mail/post.

- **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 _____

Date _____

On-Site Designated Rep. Name: _____

Designated Rep. 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
Attn: Shannon Redd

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

Notice of Federal Background Check Required

The North Carolina Department of Agriculture and Consumer Services, Food and Drug Protection Division, requires applicants of Wholesale Prescription Drug Distributors to obtain and submit a federal background check report with the license application. The Food and Drug Protection Division will consider the following factors when reviewing any criminal convictions:

- (1) The level and seriousness of the crime;
- (2) The date of the crime;
- (3) The age of the applicant at the time of the crime;
- (4) The circumstances surrounding the commission of the crime, if known;
- (5) The nexus between the criminal conduct and the prospective duties of the applicant as a licensee;
- (6) The prison, jail, probation, parole, rehabilitation, and employment records of the applicant since the date the crime was committed;
- (6a) The completion of, or active participation in, rehabilitative drug or alcohol treatment;
- (6b) A Certificate of Relief granted pursuant to N.C. Gen. Stat. § 15A-173.2;
- (7) The subsequent commission of a crime by the applicant; and
- (8) Any affidavits or other written documents, including character references.

If the Food and Drug Protection Division denies a license application based on a criminal conviction, the applicant may appeal the denial in accordance with the North Carolina Administrative Procedures Act, N.C. Gen. Stat. § 150B-1 *et seq.* The applicant may commence the denial by filing a petition for a contested case hearing with the North Carolina Office of Administrative Hearings (OAH) within sixty (60) days at:

Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6700

The petition must be in writing and in the form prescribed by N.C. Gen. Stat. § 150B-23 and accompanied by a filing fee established by OAH. The applicant must also serve a copy of the petition for a contested case hearing to:

Ms. Tina L. Hlabse
North Carolina Department of Agriculture and Consumer Services
Registered Agent and General Counsel
1001 Mail Service Center
Raleigh, NC 27699-1001

Any questions about filing a petition may be directed to the North Carolina Office of Administrative Hearings by telephone at (919) 431-3000. Information may also be obtained online at <https://www.oah.nc.gov/hearings-division>.